## **European Parliament**

2019-2024



## Plenary sitting

A9-0188/2023

22.5.2023

## \*\*\*I REPORT

on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

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

Rapporteur: Brando Benifei, Ioan-Dragoş Tudorache

(Joint committee procedure – Rule 58 of the Rules of Procedure)

Rapporteurs for the opinions of associated committees pursuant to Rule 57 of the Rules of Procedure:

Eva Maydell, Committee on Industry, Research and Energy Marcel Kolaja, Committee on Culture and Education Axel Voss, Committee on Legal Affairs

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## Symbols for procedures

\* Consultation procedure

\*\*\* Consent procedure

\*\*\*I Ordinary legislative procedure (first reading)

\*\*\*II Ordinary legislative procedure (second reading)

\*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

## Amendments to a draft act

#### Amendments by Parliament set out in two columns

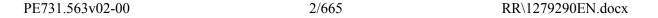
Deletions are indicated in *bold italics* in the left-hand column. Replacements are indicated in *bold italics* in both columns. New text is indicated in *bold italics* in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

## Amendments by Parliament in the form of a consolidated text

New text is highlighted in **bold italics**. Deletions are indicated using either the symbol or strikeout. Replacements are indicated by highlighting the new text in **bold italics** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.



## **CONTENTS**

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	366
OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERG	Y369
OPINION OF THE COMMITTEE ON CULTURE AND EDUCATION	416
OPINION OF THE COMMITTEE ON LEGAL AFFAIRS	457
OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALT FOOD SAFETY	
OPINION OF THE COMMITTEE ON TRANSPORT AND TOURISM	594
PROCEDURE – COMMITTEE RESPONSIBLE	663
FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE	665



## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2021)0206),
- having regard to Article 294(2) and Articles 16 and 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0146/2021),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to Rule 59 of its Rules of Procedure,
- having regard to the joint deliberations of the Committee on Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs under Rule 58 of the Rules of Procedure.
- having regard to the opinion of the Committee on Industry, Research and Energy, the Committee on Culture and Education, the Committee on Legal Affairs, the Committee on the Environment, Public Health and Food Safety and the Committee on Transport and Tourism,
- having regard to the report of the Committee on Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs (A9-0188/2023),
- 1. Adopts its position at first reading hereinafter set out;
- 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
- 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

# Proposal for a regulation Citation 4 a (new)

Text proposed by the Commission

Amendment

Having regard to the opinion of the European Central Bank,

### Amendment 2

Proposal for a regulation Citation 4 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;

## Amendment 3

## 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

### Amendment

(1) The purpose of this Regulation is to promote the uptake of human centric and trustworthy artificial intelligence and to ensure a high level of protection of health, safety, fundamental rights, democracy and rule of law and the environment from harmful effects of artificial intelligence systems in the Union while supporting 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 ensures the free

PE731.563v02-00 6/665 RR\1279290EN.docx

explicitly authorised by this Regulation.

movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of Artificial Intelligence systems (AI systems), unless explicitly authorised by this Regulation. Certain AI systems can also have an impact on democracy and rule of law and the environment. These concerns are specifically addressed in the critical sectors and use cases listed in the annexes to this Regulation.

#### Amendment 4

# Proposal for a regulation Recital 1 a (new)

Text proposed by the Commission

## Amendment

(1 a) This Regulation should preserve the values of the Union facilitating the distribution of artificial intelligence benefits across society, protecting individuals, companies, democracy and rule of law and the environment from risks while boosting innovation and employment and making the Union a leader in the field

## Amendment 5

## 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

## Amendment

(2) 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 *trustworthy and* safe and is developed and used in compliance with fundamental rights

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.

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 in order to achieve trustworthy **AI**, while divergences hampering the free circulation, innovation, deployment and *uptake* 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).

#### Amendment 6

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

## Amendment

(2 a) As artificial intelligence often relies on the processing of large volumes of data, and many AI systems and applications on the processing of personal data, it is appropriate to base this Regulation on Article 16 TFEU, which enshrines the right to the protection of natural persons with regard to the processing of personal data and provides

PE731.563v02-00 8/665 RR\1279290EN.docx

for the adoption of rules on the protection of individuals with regard to the processing of personal data.

Amendment 7

Proposal for a regulation Recital 2 b (new)

Text proposed by the Commission

Amendment

(2 b) The fundamental right to the protection of personal data is safeguarded in particular by Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive 2016/680. Directive 2002/58/EC additionally protects private life and the confidentiality of communications, including providing conditions for any personal and non-personal data storing in and access from terminal equipment. Those legal acts provide the basis for sustainable and responsible data processing, including where datasets include a mix of personal and nonpersonal data. This Regulation does not seek to affect the application of existing Union law governing the processing of personal data, including the tasks and powers of the independent supervisory authorities competent to monitor compliance with those instruments. This Regulation does not affect the fundamental rights to private life and the protection of personal data as provided for by Union law on data protection and privacy and enshrined in the Charter of Fundamental Rights of the European Union (the 'Charter').

**Amendment 8** 

Proposal for a regulation Recital 2 c (new)

## Text proposed by the Commission

#### Amendment

(2 c) Artificial intelligence systems in the Union are subject to relevant product safety legislation that provides a framework protecting consumers against dangerous products in general and such legislation should continue to apply. This Regulation is also without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety, including including Regulation (EU) 2017/2394, Regulation (EU) 2019/1020 and Directive 2001/95/EC on general product safety and Directive 2013/11/EU.

### Amendment 9

Proposal for a regulation Recital 2 d (new)

Text proposed by the Commission

### Amendment

(2 d) In accordance with Article 114(2) TFEU, this Regulation complements and should not undermine the rights and interests of employed persons. This Regulation should therefore not affect Union 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 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 should it affect concertation practices, the right to negotiate, to conclude and enforce

PE731.563v02-00 10/665 RR\1279290EN.docx

collective agreement or to take collective action in accordance with national law and/or practice. It should in any event not prevent the Commission from proposing specific legislation on the rights and freedoms of workers affected by AI systems.

#### Amendment 10

Proposal for a regulation Recital 2 e (new)

Text proposed by the Commission

Amendment

(2 e) This Regulation should not affect the provisions aiming to improve working conditions in platform work set out in Directive ... [COD 2021/414/EC].

## **Amendment 11**

Proposal for a regulation Recital 2 f (new)

Text proposed by the Commission

### Amendment

(2f)This Regulation should help in supporting research and innovation and should not undermine research and development activity and respect freedom of scientific research. It is therefore necessary to exclude from its scope AI systems specifically developed 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. Under all circumstances, any research and development activity should be carried out in accordance with the Charter, Union law as well as the national law;

### **Amendment 12**

## Proposal for a regulation Recital 3

Text proposed by the Commission

(3) Artificial intelligence is a fast evolving family of technologies that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

#### Amendment

Artificial intelligence is a fast (3) evolving family of technologies that can and already contributes to a wide array of economic, environmental and societal benefits across the entire spectrum of industries and social activities if developed in accordance with relevant general principles in line with the Charter and the values on which the Union is founded. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, food safety, education and training, media, sports, culture, infrastructure management, energy, transport and logistics, crisis management, public services, security, justice, resource and energy efficiency, environmental monitoring, the conservation and restoration of biodiversity and ecosystems and climate change mitigation and adaptation.

## **Amendment 13**

Proposal for a regulation Recital 3 a (new)

Text proposed by the Commission

### Amendment

(3 a) To contribute to reaching the carbon neutrality targets, European companies should seek to utilise all available technological advancements that can assist in realising this goal. Artificial Intelligence is a technology that has the potential of being used to process the

PE731.563v02-00 12/665 RR\1279290EN.docx

ever-growing amount of data created during industrial, environmental, health and other processes. To facilitate investments in AI-based analysis and optimisation tools, this Regulation should provide a predictable and proportionate environment for low-risk industrial solutions.

## **Amendment 14**

## 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, as well as the level of technological development, artificial intelligence may generate risks and cause harm to public or private interests and fundamental rights of natural persons that are protected by Union law. Such harm might be material or immaterial, including physical, psychological, societal or economic harm

## **Amendment 15**

## 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 and its regulatory framework to be developed according to Union values enshrined in Article 2 TEU, the fundamental rights and freedoms enshrined in the Treaties, the Charter, and international human rights law. As a pre-requisite, artificial intelligence should be a human-centric technology. It should

not substitute human autonomy or assume the loss of individual freedom and should primarily serve the needs of the society and the common good. Safeguards should be provided to ensure the development and use of ethically embedded artificial intelligence that respects Union values and the Charter

## **Amendment 16**

## 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 Council<sup>33</sup>, and it ensures the protection of ethical principles, as specifically requested by the European Parliament<sup>34</sup>.

## 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, protection of fundamental rights, democracy and rule of law and the environment, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market, the 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. These rules should be clear and robust in protecting fundamental rights, supportive of new innovative solutions, and enabling to a European ecosystem of public and private actors creating AI systems in line with Union values. 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 promoting the AI made in Europe, of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by

PE731.563v02-00 14/665 RR\1279290EN.docx

the European Council<sup>33</sup>, and it ensures the protection of ethical principles, as specifically requested by the European Parliament<sup>34</sup>.

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

### **Amendment 17**

## Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

#### Amendment

Furthermore, in order to foster the development of AI systems 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.

#### Amendment 18

Proposal for a regulation Recital 6

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

<sup>&</sup>lt;sup>34</sup> 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).

<sup>&</sup>lt;sup>34</sup> 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).

The notion of AI system should be (6) 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.

The notion of AI system *in this* (6) **Regulation** should be clearly defined and closely aligned with the work of international organisations working on artificial intelligence to ensure legal certainty, harmonization and wide *acceptance*, while providing the flexibility to accommodate the rapid technological developments in this field. Moreover, it should be based on key characteristics of artificial intelligence, such as its learning, reasoning or modelling capabilities, so as to distinguish it from simpler software systems or programming approaches. AI systems *are* designed to operate with varying levels of autonomy, *meaning that* they have at least some degree of independence of actions from human controls and of capabilities to operate without human intervention. The term "machine-based" refers to the fact that AI systems run on machines. The reference to explicit or implicit objectives underscores that AI systems can operate according to explicit human-defined objectives or to implicit objectives. The objectives of the AI system may be different from the intended purpose of the AI system in a specific context. The reference to predictions includes content, which is considered in this Regulation a form of prediction as one of the possible outputs produced by an AI system. For the purposes of this Regulation, environments should be understood as the contexts in which the AI systems operate, whereas outputs generated by the AI system, meaning predictions, recommendations or decisions, respond to the objectives of the system, on the basis of inputs from said environment. Such output further influences said environment, even by merely introducing new information to it.

PE731.563v02-00 16/665 RR\1279290EN.docx

# Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6 a) AI systems often have machine learning capacities that allow them to adapt and perform new tasks autonomously. Machine learning refers to the computational process of optimizing the parameters of a model from data, which is a mathematical construct generating an output based on input data. Machine learning approaches include, for instance, supervised, unsupervised and reinforcement learning, using a variety of methods including deep learning with neural networks. This Regulation is aimed at addressing new potential risks that may arise by delegating control to AI systems, in particular to those AI systems that can evolve after deployment. The function and outputs of many of these AI systems are based on abstract mathematical relationships that are difficult for humans to understand, monitor and trace back to specific inputs. These complex and opaque characteristics (black box element) impact accountability and explainability. Comparably simpler techniques such as knowledge-based approaches, Bayesian estimation or decision-trees may also lead to legal gaps that need to be addressed by this Regulation, in particular when they are used in combination with machine learning approaches in hybrid systems.

Amendment 20

Proposal for a regulation Recital 6 b (new)

(6 b) AI systems can be used as standalone 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 an AI component of a larger system. If this larger system would not function without the AI component in question, then the entire larger system should be considered as one single AI system under this Regulation.

#### Amendment 21

## 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 Council<sup>35</sup>, Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>36</sup> and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council<sup>37</sup>.

## Amendment

The notion of biometric data used **(7)** 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 Council<sup>35</sup>. Biometrics-based data are additional data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person, such as facial expressions, movements, pulse frequency, voice, key strikes or gait, which may or may not allow or confirm the unique identification of a natural person.

PE731.563v02-00 18/665 RR\1279290EN.docx

<sup>&</sup>lt;sup>35</sup> 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

<sup>&</sup>lt;sup>35</sup> 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).

Regulation) (OJ L 119, 4.5.2016, p. 1).

- <sup>36</sup> 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).

## **Amendment 22**

Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

Amendment

(7 a)The notion of biometric identification as used in this Regulation should be defined as 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 establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification),

irrespective of whether the individual has given its consent or not.

### Amendment 23

# Proposal for a regulation Recital 7 b (new)

Text proposed by the Commission

#### Amendment

(7 b) The notion of biometric categorisation as used in this Regulation should be defined as assigning natural persons to specific categories or inferring their characteristics and attributes 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 inferred from such data

## **Amendment 24**

## 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

The notion of remote biometric (8) 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, exlcuding verification systems which merely compare the biometric data of an individual to their previously

PE731.563v02-00 20/665 RR\1279290EN.docx

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 'realtime' 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.

## provided biometric data (one-to-one).

Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'realtime' and 'post' remote biometric identification systems. In the case of 'realtime' 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 'realtime' 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. Given that the notion of biometric identification is independent from the individual's consent, this definition applies even when warning notices are placed in the location that is under surveillance of the remote biometric identification system, and is not de facto annulled by pre-enrolment.

**Amendment 25** 

Proposal for a regulation Recital 8 a (new)

Text proposed by the Commission

Amendment

(8 a) The identification of natural persons at a distance is understood to distinguish remote biometric

identification systems from close proximity individual verification systems using biometric identification means, whose sole purpose is to confirm whether or not a specific natural person presenting themselves for identification is permitted, such as in order to gain access to a service, a device, or premises.

## **Amendment 26**

## 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 and regardless of the potential capacity restrictions. 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, sports grounds, schools, universities, relevant parts of hospitals and banks, amusement parks, festivals, 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-

PE731.563v02-00 22/665 RR\1279290EN.docx

by-case basis, having regard to the specificities of the individual situation at hand.

## **Amendment 27**

Proposal for a regulation Recital 9 a (new)

Text proposed by the Commission

#### Amendment

(9 a) It is important to note that AI systems should make best efforts to respect general principles establishing a high-level framework that promotes a coherent human-centric approach to ethical and trustworthy AI in line with the Charter of Fundamental Rights of the European Union and the values on which the Union is founded, including the protection of fundamental rights, human agency and oversight, technical robustness and safety, privacy and data governance, transparency, non-discrimination and fairness and societal and environmental wellbeing

### **Amendment 28**

Proposal for a regulation Recital 9 b (new)

Text proposed by the Commission

Amendment

(9 b) 'AI literacy' refers to skills, knowledge and understanding that allows providers, users and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause and thereby promote its democratic control. AI literacy should not be limited to learning about tools and technologies,

but should also aim to equip providers and users with the notions and skills required to ensure compliance with and enforcement of this Regulation. It is therefore necessary that the Commission, the Member States as well as providers and users of AI systems, in cooperation with all relevant stakeholders, promote the development of a sufficient level of AI literacy, in all sectors of society, for people of all ages, including women and girls, and that progress in that regard is closely followed.

### **Amendment 29**

## 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

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 nondiscriminatory 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. In order for the Union to be true to its fundamental values, AI systems intended to be used for practices that are considered unacceptable by this Regulation, should equally be deemed to be unacceptable outside the Union because of their particularly harmful effect to fundamental rights as enshrined in the Charter. Therefore it is appropriate to prohibit the export of such AI systems to third countries by providers residing in the Union.

## **Amendment 30**

## 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 Union, Europol and other EU agencies and

### Amendment

In light of their digital nature, (11)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 deployers of AI systems that are established in a third country, to the extent the output produced by those systems is *intended to be* 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

third countries and international organisations.

Union, Europol and other EU agencies and third countries and international organisations. *This exception should nevertheless be limited to trusted countries and international organisation that share Union values.* 

### Amendment 31

## Proposal for a regulation Recital 12

Text proposed by the Commission

This Regulation should also apply (12)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

This Regulation should also apply (12)to Union institutions, offices, bodies and agencies when acting as a provider or deployer 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 32**

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

Text proposed by the Commission

#### Amendment

(12 a) Software and data that are openly shared and where users can freely access, use, modify and redistribute them or modified versions thereof, can contribute to research and innovation in the market. Research by the Commission also shows that free and open-source software can

PE731.563v02-00 26/665 RR\1279290EN.docx

contribute between EUR 65 billion to EUR 95 billion to the European Union's GDP and that it can provide significant growth opportunities for the European economy. Users are allowed to run, copy, distribute, study, change and improve software and data, including models by way of free and open-source licences. To foster the development and deployment of AI, especially by SMEs, start-ups, academic research but also by individuals, this Regulation should not apply to such free and open-source AI components except to the extent that they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV of this Regulation.

## **Amendment 33**

Proposal for a regulation Recital 12 b (new)

Text proposed by the Commission

Amendment

(12 b) Neither the collaborative development of free and open-source AI components nor making them available on open repositories should constitute a placing on the market or putting into service. A commercial activity, within the understanding of making available on the market, might however be characterised by charging a price, with the exception of transactions between micro enterprises, for a free and open-source AI component but also by charging a price for technical support services, by providing a software platform through which the provider monetises other services, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software.

## Proposal for a regulation Recital 12 c (new)

Text proposed by the Commission

#### Amendment

(12 c) The developers of free and opensource AI components should not be mandated under this Regulation to comply with requirements targeting the AI value chain and, in particular, not towards the provider that has used that free and open-source AI component. Developers of free and open-source AI components should however be encouraged to implement widely adopted documentation practices, such as model and data cards, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the Union.

## **Amendment 35**

## 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 democracy and rule of law and the environment, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter, the European Green Deal, the Joint Declaration on Digital Rights of the Union and the Ethics Guidelines for Trustworthy Artificial Intelligence (AI) of the High-Level Expert Group on Artificial Intelligence, and should be nondiscriminatory and in line with the Union's international trade commitments.

## 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

#### Amendment 37

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

## Amendment

(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 abusive* 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, data protection and privacy and the rights of the child.

## **Amendment 38**

## 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 humanmachine 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 materially distorting human behaviour, whereby physical or psychological 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 insofar as they are materially distorting the behaviour of a natural person in a manner that causes or is likely to cause that person or another person significant harm. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of individuals and specific groups of persons due to their known or predicted personality traits, age, physical or mental incapacities, social or economic situation. They do so with the intention to *or the* effect of materially distorting the behaviour of a person and in a manner that causes or is likely to cause significant 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, such as factors that may not be reasonably foreseen and mitigated by the provider or the deployer of the AI system. In any case, it is not necessary for the provider or the deployer to have the intention to cause the significant 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 2005/29/EC, according to which unfair

PE731.563v02-00 30/665 RR\1279290EN.docx

commercial practices are prohibited, irrespective of whether they carried out having recourse to AI systems or otherwise. In such setting, lawful commercial practices, for example in the field of advertising, that are in compliance with Union law should not in themselves be regarded as violating prohibition. 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 humanmachine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research and on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.

**Amendment 39** 

Proposal for a regulation Recital 16 a (new)

Text proposed by the Commission

Amendment

(16 a) AI systems that categorise natural persons by assigning them to specific categories, according to known or inferred sensitive or protected characteristics are particularly intrusive, violate human dignity and hold great risk of discrimination. Such characteristics include gender, 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 Charter of Fundamental Rights of the European Union, as well as under Article 9 of Regulation (EU)2016/769. Such systems should therefore be prohibited.

## Proposal for a regulation Recital 17

Text proposed by the Commission

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 nondiscrimination 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

AI systems providing social scoring of natural persons for general purpose 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 or groups based on multiple data points and time occurrences 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 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 41**

## 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

### Amendment

(18) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces *is* particularly intrusive *to* the rights and freedoms of the concerned persons, *and can ultimately* affect the private life of a large part of the population, evoke a feeling of constant surveillance, *give* parties deploying biometric identification in publicly accessible spaces a position of uncontrollable power and indirectly

PE731.563v02-00 32/665 RR\1279290EN.docx

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.

dissuade the exercise of the freedom of assembly and other fundamental rights at the core to the Rule of Law. 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, 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. Similarly, AI systems used for the analysis of recorded footage of publicly accessible spaces through 'post' remote biometric identification systems should also be prohibited, unless there is pre-judicial authorisation for use in the context of law enforcement, when strictly necessary for the targeted search connected to a specific serious criminal offense that already took place, and only subject to a pre-judicial authorisation.

## **Amendment 42**

## 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

Amendment

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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/JHA<sup>38</sup> 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.

## **Amendment 43**

Proposal for a regulation Recital 20

<sup>&</sup>lt;sup>38</sup> 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).

In order to ensure that those *(20)* 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.

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## **Amendment 44**

## Proposal for a regulation Recital 21

Text proposed by the Commission

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(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

Amendment

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 45**

## Proposal for a regulation Recital 22

Text proposed by the Commission

Amendment

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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## **Amendment 46**

## Proposal for a regulation Recital 23

Text proposed by the Commission

Amendment

(23) The use of AI systems for 'real-

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PE731.563v02-00 36/665 RR\1279290EN.docx

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 47

Proposal for a regulation Recital 24

# Text proposed by the Commission

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 'realtime' 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 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.

#### **Amendment 48**

# Proposal for a regulation Recital 25

Text proposed by the Commission

In accordance with Article 6a of (25)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 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.

### 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), of this Regulation adopted on the basis of Article 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.

### **Amendment 49**

# 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 50

# Proposal for a regulation Recital 26 a (new)

Text proposed by the Commission

### 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.

### Amendment

(26 a) AI systems used by law enforcement authorities or on their behalf to make predictions, profiles or risk assessments based on profiling of natural persons or data analysis based on personality traits and characteristics, including the person's location, or past criminal behaviour of natural persons or groups of persons for the purpose of predicting the occurrence or reoccurrence of an actual or potential criminal offence(s) or other criminalised social behaviour or administrative offences, including fraud-predicition systems, 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.

#### Amendment 51

Proposal for a regulation Recital 26 b (new)

Text proposed by the Commission

Amendment

(26 b) The indiscriminate and untargeted scraping of biometric data from social media or CCTV footage to create or expand facial recognition databases add to the feeling of mass surveillance and can lead to gross violations of fundamental rights, including the right to privacy. The use of AI systems with this intended purpose should therefore be prohibited.

# **Amendment 52**

Proposal for a regulation Recital 26 c (new)

Text proposed by the Commission

Amendment

(26 c) There are serious concerns about the scientific basis of AI systems aiming to detect emotions, physical or physiological features such as facial expressions, movements, pulse frequency or voice. Emotions or expressions of emotions and perceptions thereof vary considerably across cultures and situations, and even within a single individual. 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 physical or physiological movements), the lack of specificity (physical or physiological expressions do not perfectly match emotion categories) and the limited generalisability (the effects of context and culture are not

PE731.563v02-00 40/665 RR\1279290EN.docx

sufficiently considered). Reliability issues and consequently, major risks for abuse, may especially arise when deploying the system in real-life situations related to law enforcement, border management, workplace and education institutions. Therefore, the placing on the market, putting into service, or use of AI systems intended to be used in these contexts to detect the emotional state of individuals should be prohibited.

#### Amendment 53

# Proposal for a regulation Recital 26 d (new)

Text proposed by the Commission

#### Amendment

(26 d) Practices that are prohibited by Union legislation, including data protection law, non-discrimination law, consumer protection law, and competition law, should not be affected by this Regulation

### Amendment 54

# 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, 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, *including* fundamental rights, democracy, the rule or law or the environment. In order to ensure alignment with sectoral legislation

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

and avoid duplications, requirements for high-risk AI systems should take into account sectoral legislation laying down requirements for high-risk AI systems included in the scope of this Regulation, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices or Directive 2006/42/EC on Machinery. 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. Given the rapid pace of technological development, as well as the potential changes in the use of AI systems, the list of high-risk areas and use-cases in Annex III should nonetheless be subject to permanent review through the exercise of regular assessment.

# **Amendment 55**

# Proposal for a regulation Recital 28

Text proposed by the Commission

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

# Amendment

AI systems could have an adverse *impact* to health and safety of persons, in particular when such systems operate as safety 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

PE731.563v02-00 42/665 RR\1279290EN.docx

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.

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.

**Amendment 56** 

Proposal for a regulation Recital 28 a (new)

(28 a) 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 nondiscrimination, right to education consumer protection, workers' rights, rights of persons with disabilities, gender equality, intellectual property rights, 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 to the environment.

**Amendment 57** 

Proposal for a regulation Recital 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 Council<sup>39</sup>, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>40</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>41</sup>, Directive 2014/90/EU of the European Parliament and of the Council<sup>42</sup>, Directive (EU) 2016/797 of the European Parliament and of the Council<sup>43</sup>, Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>44</sup>, Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>45</sup>, and Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>46</sup>, 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 Council<sup>39</sup>, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>40</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>41</sup>, Directive 2014/90/EU of the European Parliament and of the Council<sup>42</sup>, Directive (EU) 2016/797 of the European Parliament and of the Council<sup>43</sup>, Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>44</sup>, Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>45</sup>, and Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>46</sup>, 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.

<sup>&</sup>lt;sup>39</sup> 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).

<sup>&</sup>lt;sup>40</sup> 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).

<sup>&</sup>lt;sup>39</sup> 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).

<sup>&</sup>lt;sup>40</sup> 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).

- <sup>41</sup> 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).
- <sup>42</sup> 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).
- <sup>43</sup> 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).
- <sup>44</sup> 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).
- <sup>45</sup> 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).
- <sup>46</sup> 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

- <sup>41</sup> 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).
- <sup>42</sup> 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).
- <sup>43</sup> 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).
- <sup>44</sup> 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).
- <sup>45</sup> 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).
- <sup>46</sup> 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).

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).

# **Amendment 58**

# 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 law listed 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 in order to ensure compliance with essential safety requirements with a third-party conformity assessment body pursuant to that relevant Union harmonisation *law*. 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 59**

# Proposal for a regulation Recital 31

Text proposed by the Commission

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 Council<sup>47</sup> and Regulation (EU) 2017/746 of the European Parliament and of the Council<sup>48</sup>, where a third-party conformity assessment is provided for medium-risk and high-risk products.

### Amendment 60

Proposal for a regulation Recital 32

### Amendment

as high-risk pursuant to this Regulation should 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 *law* that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>47</sup> and Regulation (EU) 2017/746 of the European Parliament and of the Council<sup>48</sup>, where a third-party conformity assessment is provided for medium-risk and high-risk products.

<sup>&</sup>lt;sup>47</sup> 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).

<sup>&</sup>lt;sup>48</sup> 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).

<sup>&</sup>lt;sup>47</sup> 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).

<sup>&</sup>lt;sup>48</sup> 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).

# Text proposed by the Commission

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 predefined 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

As regards stand-alone AI systems, (32)meaning high-risk AI systems other than those that are safety components of products, or which are themselves products and that are listed in one of the areas and use cases in Annex III, 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 and, where the AI system is used as a safety component of a critical infrastructure, to the environment. Such significant risk of harm should be identified by assessing on the one hand the effect of such risk with respect to its *level of* severity, *intensity*, probability of occurrence and duration combined altogether and on the other hand whether the risk can affect an individual, a plurality of persons or a particular group of persons. Such combination could for instance result in a high severity but low probability to affect a natural person, or a high probability to affect a group of persons with a low intensity over a long period of time, depending on the context. 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 61**

Proposal for a regulation Recital 32 a (new)

Text proposed by the Commission

# Amendment

(32 a) Providers whose AI systems fall under one of the areas and use cases listed in Annex III that consider their system does not pose a significant risk of harm to the health, safety, fundamental rights or the environment should inform

the national supervisory authorities by submitting a reasoned notification. This could take the form of a one-page summary of the relevant information on the AI system in question, including its intended purpose and why it would not pose a significant risk of harm to the health, safety, fundamental rights or the environment. The Commission should specify criteria to enable companies to assess whether their system would pose such risks, as well as develop an easy to use and standardised template for the notification. Providers should submit the notification as early as possible and in any case prior to the placing of the AI system on the market or its putting into service, ideally at the development stage, and they should be free to place it on the market at any given time after the notification. However, if the authority estimates the AI system in question was misclassified, it should object to the notification within a period of three months. The objection should be substantiated and duly explain why the AI system has been misclassified. The provider should retain the right to appeal by providing further arguments. If after the three months there has been no objection to the notification, national supervisory authorities could still intervene if the AI system presents a risk at national level, as for any other AI system on the market. National supervisory authorities should submit annual reports to the AI Office detailing the notifications received and the decisions taken.

**Amendment 62** 

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

#### Amendment 63

Proposal for a regulation Recital 33 a (new)

Text proposed by the Commission

Amendment

(33 a) As biometric data constitute a special category of sensitive personal data in accordance with Regulation 2016/679, it is appropriate to classify as high-risk several critical use-cases of biometric and biometrics-based systems. AI systems intended to be used for biometric identification of natural persons and AI systems intended to be used to make inferences about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems, with the exception of those which are prohibited under this Regulation should therefore be classified as high-risk. This should not include AI systems intended to be used for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of

having access to a service, a device or premises (one-to-one verification). Biometric and biometrics-based systems which are provided for under Union law to enable cybersecurity and personal data protection measures should not be considered as posing a significant risk of harm to the health, safety and fundamental rights.

#### Amendment 64

# 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

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 the supply of water, gas, heating electricity and critical digital infrastructure, since their failure or malfunctioning may infringe the security and integrity of such critical infrastructure or 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. Safety components of critical infrastructure, including critical digital infrastructure, are systems used to directly protect the physical integrity of physical infrastructure or health and safety of persons and property. Failure or malfunctioning of such components might directly lead to risks to the physical integrity of critical infrastructure and thus to risks to the health and safety of persons and property. Components intended to be used solely for cybersecurity purposes should not qualify as safety components. Examples of such safety components may include systems for monitoring water pressure or fire alarm controlling systems in cloud

PE731.563v02-00 52/665 RR\1279290EN.docx

### computing centres.

#### Amendment 65

# Proposal for a regulation Recital 35

Text proposed by the Commission

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

Deployment of AI systems in (35)education is important in order to help modernise entire education systems, to increase educational quality, both offline and online and to accelerate digital education, thus also making it available to a broader audience. AI systems used in education or vocational training, notably for determining access or materially influence decisions on admission 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 or to assess the appropriate level of education for an individual and materially influence the level of education and training that individuals will receive or be able to access or to monitor and detect prohibited behaviour of students during tests should be classified as high-risk AI systems, 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 can be particularly intrusive and may violate the right to education and training as well as the right not to be discriminated against and 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.

### **Amendment 66**

# Proposal for a regulation Recital 36

Text proposed by the Commission

AI systems used in employment, (36)workers management and access to selfemployment, 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

AI systems used in employment, (36)workers management and access to selfemployment, notably for the recruitment and selection of persons, for making decisions or materially influence decisions on initiation, promotion and termination and for *personalised* task allocation *based* on individual behaviour, personal traits 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, livelihoods of these persons and workers' rights. 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 impact their 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.

**Amendment 67** 

Proposal for a regulation Recital 37

PE731.563v02-00 54/665 RR\1279290EN.docx

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, nondiscrimination, 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

Another area in which the use of AI (37)systems deserves special consideration is the access to and enjoyment of certain essential private and public services, including healthcare services, and essential services, including but not limited to housing, electricity, heating/cooling and internet, 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, gender, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. However, AI systems provided for by Union law for the purpose of detecting fraud in the offering of financial services should not be considered as high-risk under this **Regulation.** Natural persons applying for or receiving public assistance benefits and services from public authorities, including healthcare services and essential services, including but not limited to housing, electricity, heating/cooling and internet, 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, nondiscrimination, human dignity or an

RR\1279290EN.docx 55/665 PE731.563v02-00

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.

effective remedy. Similarly, AI systems intended to be used to make decisions or materially influence decisions on the eligibility of natural persons for health and life insurance may also have a significant impact on persons' livelihood and may infringe their fundamental rights such as by limiting access to healthcare or by perpetuating discrimination based on personal characteristics. 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 evaluate and classify emergency calls by natural persons or 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 68**

Proposal for a regulation Recital 37 a (new)

Text proposed by the Commission

Amendment

(37 a) 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, some specific use-cases of AI applications in law enforcement has to be classified as high-risk, in particular in instances where there is the potential to significantly affect the lives or the fundamental rights of individuals.

### **Amendment 69**

# Proposal for a regulation Recital 38

Text proposed by the Commission

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

### Amendment

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, 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 *or on behalf of* law enforcement authorities or by Union agencies, offices or bodies in support of law enforcement authorities, as polygraphs and similar tools insofar as

RR\1279290EN.docx 57/665 PE731.563v02-00

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.

their use is permitted under relevant Union and national law, 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 classified as high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences. 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.

### Amendment 70

# 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, nondiscrimination, protection of private life and personal data, international protection and good administration. It is therefore

### 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, nondiscrimination, protection of private life and personal data, international protection and good administration. It is therefore

PE731.563v02-00 58/665 RR\1279290EN.docx

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 Council<sup>49</sup>, the Regulation (EC) No 810/2009 of the European Parliament and of the Council<sup>50</sup> and other relevant legislation.

appropriate to classify as high-risk AI systems intended to be used by or on behalf of competent public authorities or by Union agencies, offices or bodies charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools insofar as their use is permitted under relevant Union and national law, 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 and assessment of the veracity of evidence in relation to 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; for monitoring, surveilling or processing personal data in the context of border management activities, for the purpose of detecting, recognising or identifying natural persons; for the forecasting or prediction of trends related to migration movements and border crossings. 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<sup>49</sup>, the Regulation (EC) No 810/2009 of the European Parliament and of the Council<sup>50</sup> and other relevant legislation. The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or Union institutions, agencies or bodies 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 or deny safe and

effective legal avenues into the territory of the Union, including the right to international protection.

# 5.9.2009, p. 1).

### Amendment 71

# Proposal for a regulation Recital 40

Text proposed by the Commission

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

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 be used by a judicial authority or administrative body or on their behalf to assist judicial authorities or administrative **bodies** in researching and interpreting facts and the law and in applying the law to a concrete set of facts or used in a similar way in alternative dispute resolution. The use of artificial intelligence tools can support, but should replace the decisionmaking power of judges or judicial independence, as the final decisionmaking must remain a human-driven activity and decision. Such qualification should not extend, however, to AI systems

PE731.563v02-00 60/665 RR\1279290EN.docx

<sup>&</sup>lt;sup>49</sup> 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).

<sup>&</sup>lt;sup>50</sup> 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).

<sup>&</sup>lt;sup>49</sup> 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).

<sup>&</sup>lt;sup>50</sup> 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).

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 72**

Proposal for a regulation Recital 40 a (new)

Text proposed by the Commission

### Amendment

(40 a) In order to address the risks of undue external interference to the right to vote enshrined in Article 39 of the Charter, and of disproportionate effects on democratic processes, democracy, and the rule of law, AI systems intended to be used to influence the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda should be classified as high-risk AI systems. with the exception of AI systems whose output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistical point of view.

### Amendment 73

Proposal for a regulation Recital 40 b (new)

Text proposed by the Commission

Amendment

(40 b) Considering the scale of natural persons using the services provided by social media platforms designated as very large online platforms, such online platforms can be used in a way that

strongly influences safety online, the shaping of public opinion and discourse, election and democratic processes and societal concerns. It is therefore appropriate that AI systems used by those online platforms in their recommender systems are subject to this Regulation so as to ensure that the AI systems comply with the requirements laid down under this Regulation, including the technical requirements on data governance, technical documentation and traceability, transparency, human oversight, accuracy and robustness. Compliance with this Regulation should enable such very large online platforms to comply with their broader risk assessment and riskmitigation obligations in Article 34 and 35 of Regulation EU 2022/2065. The obligations in this Regulation are without prejudice to Regulation (EU) 2022/2065 and should complement the obligations required under the Regulation (EU) 2022/2065 when the social media platform has been designated as a very large online platform. Given the European-wide impact of social media platforms designated as very large online platforms, the authorities designated under Regulation (EU) 2022/2065 should act as enforcement authorities for the purposes of enforcing this provision.

## **Amendment 74**

# 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* 

### Amendment

(41) The fact that an AI system is classified as *a* high risk *AI system* under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful *or unlawful* 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

PE731.563v02-00 62/665 RR\1279290EN.docx

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.

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.

### Amendment 75

# Proposal for a regulation Recital 41 a (new)

Text proposed by the Commission

# Amendment

(41 a) A number of legally binding rules at European, national and international level already apply or are relevant to AI systems today, including but 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, antidiscrimination 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 national law. 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).

### Amendment 76

# 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 affected persons, certain mandatory requirements should apply, taking into account the intended purpose, *the* reasonably foreseeable misuse of the system and according to the risk management system to be established by the provider. These requirements should be objective-driven, fit for purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators.

#### Amendment 77

# Proposal for a regulation Recital 43

Text proposed by the Commission

(43) Requirements should apply to highrisk 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

Requirements should apply to highrisk AI systems as regards the quality and relevance of data sets used, technical documentation and record-keeping, transparency and the provision of information to *deployers*, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as well as the environment, democracy and rule of law, as applicable in the light of the intended purpose or reasonably foreseeable misuse of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

### **Amendment 78**

PE731.563v02-00 64/665 RR\1279290EN.docx

# Proposal for a regulation Recital 44

Text proposed by the Commission

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 shouldbe 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 highrisk AI systems.

#### Amendment

(44)Access to data of high quality plays a vital role in providing structure and in ensuring 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, and where applicable, validation and testing data sets, including the labels, should be sufficiently relevant, representative, appropriately vetted for errors and as complete as possible 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 in relation to whom the high-risk AI system is intended to be used, with specific attention to the mitigation of possible biases in the datasets, that might lead to risks to fundamental rights or discriminatory outcomes for the persons affected by the high-risk AI system. Biases can for example 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. Results provided by AI systems are influenced by such inherent biases that are inclined to gradually increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain vulnerable or ethnic groups, or racialised communities. In particular, training, validation and testing data sets should take into account,

RR\1279290EN.docx 65/665 PE731.563v02-00

to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, contextal, 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, exceptionally and following the application of all applicable conditions laid down under this Regulation and in Regulation (EU) 2016/679, Directive (EU) 2016/680 and **Regulation (EU) 2018/1725,** be able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the negative bias detection and correction in relation to highrisk AI systems. Negative bias should be understood as bias that create direct or indirect discriminatory effect against a natural person The requirements related to data governance can be complied with by having recourse to third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices.

# Amendment 79

# 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

### Amendment

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

PE731.563v02-00 66/665 RR\1279290EN.docx

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 nondiscriminatory 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.

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 nondiscriminatory 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 80**

Proposal for a regulation Recital 45 a (new)

Text proposed by the Commission

#### Amendment

(45 a) The right to privacy and to protection of personal data must be guaranteed throughout the entire lifecycle of the AI system. In this regard, the principles of data minimisation and data protection by design and by default, as set out in Union data protection law, are essential when the processing of data involves significant risks to the fundamental rights of individuals. Providers and users of AI systems should implement state-of-the-art technical and organisational measures in order to protect those rights. Such measures should include not only anonymisation and encryption, but also the use of increasingly available technology that permits algorithms to be brought to the data and allows valuable insights to be derived without the transmission between parties or unnecessary copying of the raw

#### Amendment 81

# Proposal for a regulation Recital 46

Text proposed by the Commission

Having information on how highrisk 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

Having *comprehensible* (46)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. 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 appropriately throughout the lifecycle of the AI system. AI systems can have a large important environmental impact and high energy consumption during their lifecyle. In order to better apprehend the impact of AI systems on the environment, the technical documentation drafted by providers should include information on the energy consumption of the AI system, including the consumption during development and expected consumption during use. Such information should take into account the relevant Union and national legislation. This reported information should be comprehensible, comparable and verifiable and to that end, the Commission should develop guidelines on a harmonised metholodogy for calculation and reporting of this information. To ensure that a single documentation is

PE731.563v02-00 68/665 RR\1279290EN.docx

possible, terms and definitions related to the required documentation and any required documentation in the relevant Union legislation should be aligned as much as possible.

### **Amendment 82**

Proposal for a regulation Recital 46 a (new)

Text proposed by the Commission

Amendment

(46 a) AI systems should take into account state-of-the art methods and relevant applicable standards to reduce the energy use, resource use and waste, as well as to increase their energy efficiency and the overall efficiency of the system. The environmental aspects of AI systems that are significant for the purposes of this Regulation are the energy consumption of the AI system in the development, training and deployment phase as well as the recording and reporting and storing of this data. The design of AI systems should enable the measurement and logging of the consumption of energy and resources at each stage of development, training and deployment. The monitoring and reporting of the emissions of AI systems must be robust, transparent, consistent and accurate. In order to ensure the uniform application of this Regulation and stable legal ecosystem for providers and deployers in the Single Market, the Commission should develop a common specification for the methodology to fulfil the reporting and documentation requirement on the consumption of energy and resources during development, training and deployment. Such common specifications on measurement methodology can develop a baseline upon which the Commission can better decide if future regulatory interventions are needed, upon conducting an impact

assessment that takes into account existing law.

**Amendment 83** 

Proposal for a regulation Recital 46 b (new)

Text proposed by the Commission

Amendment

(46 b) In order to achieve the objectives of this Regulation, and contribute to the Union's environmental objectives while ensuring the smooth functioning of the internal market, it may be necessary to establish recommendations and guidelines and, eventually, targets for sustainability. For that purpose the Commission is entitled to develop a methodology to contribute towards having Kev Performance Indicators (KPIs) and a reference for the Sustainable Development Goals (SDGs). The goal should be in the first instance to enable fair comparison between AI implementation choices providing incentives to promote using more efficient AI technologies addressing energy and resource concerns. To meet this objective this Regulation should provide the means to establish a baseline collection of data reported on the emissions from development and training and for deployment;

**Amendment 84** 

Proposal for a regulation Recital 47 a (new)

Text proposed by the Commission

Amendment

(47a) Such requirements on transparency and on the explicability of AI decision-making should also help to counter the deterrent effects of digital

PE731.563v02-00 70/665 RR\1279290EN.docx

asymmetry and so-called 'dark patterns' targeting individuals and their informed consent.

#### Amendment 85

# 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 and cybersecurity in accordance with the generally acknowledged state of the art. Performance metrics and their expected level should be defined with the primary objective to mitigate risks and negative impact of the AI system. The expected level of *performance* metrics should be communicated in a clear, transparent, easily understandable and intelligible way to the deployers. The declaration of performance metrics cannot be considered proof of future levels, but relevant methods need to be applied to ensure consistent levels during use While standardisation organisations exist to establish standards, coordination on benchmarking is needed to establish how these standardised requirements and characteristics of AI systems should be measured. The European Artificial Intelligence Office should bring together national and international metrology and benchmarking authorities and provide non-binding guidance to address the technical aspects of how to measure the appropriate levels of performance and robustness.

# **Amendment 86**

# 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 outputs generated by the AI system.

#### Amendment

(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 outputs generated by the AI system. Users of the AI system should take steps to ensure that the possible trade-off between robustness and accuracy does not lead to discriminatory or negative outcomes for minority subgroups.

### **Amendment 87**

# Proposal for a regulation Recital 51

# Text proposed by the Commission

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

### Amendment

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 confidentiality 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

PE731.563v02-00 72/665 RR\1279290EN.docx

of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

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. High-risk AI should be accompanied by security solutions and patches for the lifetime of the product, or in case of the absence of dependence on a specific product, for a time that needs to be stated by the manufacturer.

#### **Amendment 88**

Proposal for a regulation Recital 53 a (new)

Text proposed by the Commission

### Amendment

(53 a) As signatories to the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), the Union and the Member States are legally obliged to protect persons with disabilities from discrilmination and promote their equality, to ensure that persons with disabilities have access, on an equal basis wirh others, to information and communications technologies and systems, and to ensure respect for privacy for persons with disabilities. Given the growing importance and use of AI systems, the 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 therefore essential that Providers ensure full compliance with accessibility requirements, including Directive (EU) 2016/2102 and Directive (EU) 2019/882. Providers should ensure compliance with these requirements by design. Therefore, the necessary measures should be integrated as much as possible

#### **Amendment 89**

## Proposal for a regulation Recital 54

Text proposed by the Commission

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 and establish a robust post-market monitoring system. *For* providers that have already in place quality management systems based on standards such as ISO 9001 or other relevant standards, no duplicative quality management system in full should be expected but rather an adaptation of their existing systems to certain aspects linked to compliance with specific requirements of this Regulation. This should also be reflected in future standardization activities or guidance adopted by the Commission in this respect. 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 90

# Proposal for a regulation Recital 56

Text proposed by the Commission

(56) To enable enforcement of this Regulation and create a level-playing field

Amendment

(56) To enable enforcement of this Regulation and create a level-playing field

PE731.563v02-00 74/665 RR\1279290EN.docx

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.

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.

### **Amendment 91**

## 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, as appropriate.

### **Amendment 92**

Proposal for a regulation Recital 58 a (new)

Text proposed by the Commission

### Amendment

(58 a) Whilst risks related to AI systems can result from the way such systems are designed, risks can as well stem from how

such AI systems are used. Deployers 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. Deployers are best placed to understand how the highrisk AI system will be used concretely and can therefore identify potential significant risks that were not foreseen in the development phase, due 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. Deployers should identify appropriate governance structures in that specific context of use, such as arrangements for human oversight, complaint-handling procedures and redress procedures, because choices in the governance structures can be instrumental in mitigating risks to fundamental rights in concrete use-cases. In order to efficiently ensure that fundamental rights are protected, the deployer of high-risk AI systems should therefore carry out a fundamental rights impact assessment 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 at the latest from the time of putting it into use. If such plan cannot be identified, the deployer should refrain from putting the system into use. When performing this impact assessment, the deployer should notify the national supervisory authority and, to the best extent possible relevant stakeholders as well as 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 and are encouraged to make the summary of their fundamental rights impact assessment publicly available on their online website. This obligations should not apply to

PE731.563v02-00 76/665 RR\1279290EN.docx

SMEs which, given the lack of resrouces, might find it difficult to perform such consultation. Nevertheless, they should also strive to invole such representatives when carrying out their fundamental rights impact assessment. In addition, given the potential impact and the need for democratic oversight and scrutiny, deployers of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies, as well deployers who are undertakings designated as a gatekeeper under Regulation (EU) 2022/1925 should be required to register the use of any highrisk AI system in a public database. Other deployers may voluntarily register.

### **Amendment 93**

## 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 94

# 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

### 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.

## Amendment

(60) Within the AI value chain multiple entities often supply tools and services but also components or processes that are then incorporated by the provider into the AI system, including in relation to data collection and pre-processing, model

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.

training, model retraining, model testing and evaluation, integration into software, or other aspects of model development. The involved entities may make their offering commercially available directly or indirectly, through interfaces, such as **Application Programming Interfaces** (API), and distributed under free and open source licenses but also more and more by AI workforce platforms, trained parameters resale, DIY kits to build models or the offering of paying access to a model serving architecture to develop and train models. In the light of this complexity of the AI value chain, all relevant third parties, in particular those that are involved in the development, sale and the *commercial* supply of software tools, components, pre-trained models or data incorporated into the AI system, or providers of network services, should without compromising their own intellectual property rights or trade secrets, make available the required information, training or expertise and cooperate, as appropriate, with providers to enable their control over all compliance relevant aspects of the AI system that falls under this Regulation. To allow a costeffective AI value chain governance, the level of control shall be explicitly disclosed by each third party that supplies the provider with a tool, service, component or process that is later incorporated by the provider into the AI system.

Amendment 95

Proposal for a regulation Recital 60 a (new)

Text proposed by the Commission

Amendment

(60 a) Where one party is in a stronger bargaining position, there is a risk that that party could leverage such position to the detriment of the other contracting

party when negotiating the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations. Such contractual imbalances particularly harm micro, small and medium-sized enterprises as well as start-ups, unless they are owned or sub-contracted by an enterprise which is able to compensate the sub-contractor appropriately, as they are without a meaningful ability to negotiate the conditions of the contractual agreement, and may have no other choice than to accept 'take-it-or-leave-it' contractual terms. Therefore, unfair contract terms regulating the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations should not be binding to such micro, small or medium-sized enterprises and start-ups when they have been unilaterally imposed on them.

**Amendment 96** 

Proposal for a regulation Recital 60 b (new)

Text proposed by the Commission

Amendment

(60 b) Rules on contractual terms should take into account the principle of contractual freedom as an essential concept in business-to-business relationships. Therefore, not all contractual terms should be subject to an unfairness test, but only to those terms that are unilaterally imposed on micro, small and medium-sized enterprises and start-ups. This concerns 'take-it-or-leave-it' situations where one party supplies a certain contractual term and the micro, small or medium-sized enterprise and start-up cannot influence the content of that term despite an attempt to negotiate

it. A contractual term that is simply provided by one party and accepted by the micro, small, medium-sized enterprise or a start-up or a term that is negotiated and subsequently agreed in an amended way between contracting parties should not be considered as unilaterally imposed.

### Amendment 97

Proposal for a regulation Recital 60 c (new)

Text proposed by the Commission

Amendment

(60 c) Furthermore, the rules on unfair contractual terms should only apply to those elements of a contract that are related to supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations. Other parts of the same contract, unrelated to these elements, should not be subject to the unfairness test laid down in this Regulation.

### **Amendment 98**

Proposal for a regulation Recital 60 d (new)

Text proposed by the Commission

Amendment

(60 d) Criteria to identify unfair contractual terms should be applied only to excessive contractual terms, where a stronger bargaining position is abused. The vast majority of contractual terms that are commercially more favourable to one party than to the other, including those that are normal in business-to-business contracts, are a normal expression of the principle of contractual freedom and continue to apply. If a

PE731.563v02-00 80/665 RR\1279290EN.docx

contractual term is not included in the list of terms that are always considered unfair, the general unfairness provision applies. In this regard, the terms listed as unfair terms should serve as a yardstick to interpret the general unfairness provision.

**Amendment 99** 

Proposal for a regulation Recital 60 e (new)

Text proposed by the Commission

Amendment

(60 e) Foundation models are a recent development, in which AI models are developed from algorithms designed to optimize for generality and versatility of output. Those models are often trained on a broad range of data sources and large amounts of data to accomplish a wide range of downstream tasks, including some for which they were not specifically developed and trained. The foundation model can be unimodal or multimodal, trained through various methods such as supervised learning or reinforced learning. AI systems with specific intended purpose or general purpose AI systems can be an implementation of a foundation model, which means that each foundation model can be reused in countless downstream AI or general purpose AI systems. These models hold growing importance to many downstream applications and systems.

**Amendment 100** 

Proposal for a regulation Recital 60 f (new)

Text proposed by the Commission

Amendment

(60 f) In the case of foundation models provided as a service such as through API

access, the cooperation with downstream providers should extend throughout the time during which that service is provided and supported, in order to enable appropriate risk mitigation, unless the provider of the foundation model transfers the training model as well as extensive and appropriate information on the datasets and the development process of the system or restricts the service, such as the API access, in such a way that the downstream provider is able to fully comply with this Regulation without further support from the original provider of the foundation model.

### **Amendment 101**

Proposal for a regulation Recital 60 g (new)

Text proposed by the Commission

Amendment

(60 g) In light of the nature and complexity of the value chain for AI system, it is essential to clarify the role of actors contributing to the development of AI systems. There is significant uncertainty as to the way foundation models will evolve, both in terms of typology of models and in terms of selfgovernance. Therefore, it is essential to clarify the legal situation of providers of foundation models. Combined with their complexity and unexpected impact, the downstream AI provider's lack of control over the foundation model's development and the consequent power imbalance and in order to ensure a fair sharing of responsibilities along the AI value chain, such models should be subject to proportionate and more specific requirements and obligations under this Regulation, namely foundation models should assess and mitigate possible risks and harms through appropriate design, testing and analysis, should implement data governance measures, including

PE731.563v02-00 82/665 RR\1279290EN.docx

assessment of biases, and should comply with technical design requirements to ensure appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity and should comply with environmental standards. These obligations should be accompanied by standards. Also, foundation models should have information obligations and prepare all necessary technical documentation for potential downstream providers to be able to comply with their obligations under this Regulation. Generative foundation models should ensure transparency about the fact the content is generated by an AI system, not by humans. These specific requirements and obligations do not amount to considering foundation models as high risk AI systems, but should guarantee that the objectives of this Regulation to ensure a high level of protection of fundamental rights, health and safety, environment, democracy and rule of law are achieved. Pre-trained models developed for a narrower, less general, more limited set of applications that cannot be adapted for a wide range of tasks such as simple multi-purpose AI systems should not be considered foundation models for the purposes of this Regulation, because of their greater interpretability which makes their behaviour less unpredictable.

### **Amendment 102**

Proposal for a regulation Recital 60 h (new)

Text proposed by the Commission

Amendment

(60 h) Given the nature of foundation models, expertise in conformity assessment is lacking and third-party auditing methods are still under development. The sector itself is therefore developing new ways to assess

fundamental models that fulfil in part the objective of auditing (such as model evaluation, red-teaming or machine learning verification and validation techniques). Those internal assessments for foundation models should be should be broadly applicable (e.g. independent of distribution channels, modality, development methods), to address risks specific to such models taking into account industry state-of-the-art practices and focus on developing sufficient technical understanding and control over the model, the management of reasonably foreseeable risks, and extensive analysis and testing of the model through appropriate measures, such as by the involvement of independent evaluators. As foundation models are a new and fastevolving development in the field of artificial intelligence, it is appropriate for the Commission and the AI Office to monitor and periodically asses the legislative and governance framework of such models and in particular of generative AI systems based on such models, which raise significant questions related to the generation of content in breach of Union law, copyright rules, and potential misuse. It should be clarified that this Regulation should be without prejudice to Union law on copyright and related rights, including Directives 2001/29/EC, 2004/48/ECR and (EU) 2019/790 of the European Parliament and of the Council.

### **Amendment 103**

## 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

Amendment

(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised

PE731.563v02-00 84/665 RR\1279290EN.docx

standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>54</sup> 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.

standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council/11 should be a means for providers to demonstrate conformity with the requirements of this Regulation. To ensure the effectiveness of standards as policy tool for the Union and considering the importance of standards for ensuring conformity with the requirements of this Regulation and for the competitiveness of undertakings, it is necessary to ensure a balanced representation of interests by involving all relevant stakeholders in the development of standards. The standardisation process should be transparent in terms of legal and natural persons participating in the standardisation activities.

## **Amendment 104**

Proposal for a regulation Recital 61 a (new)

Text proposed by the Commission

Amendment

(61 a) In order to facilitate compliance, the first standardisation requests should be issued by the Commission two months after the entry into force of this Regulation at the latest. This should serve to improve legal certainty, thereby

<sup>54</sup> 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).

<sup>54</sup> 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).

promoting investment and innovation in AI, as well as competitiveness and growth of the Union market, while enhancing multistakeholder governance representing all relevant European stakeholders such as the AI Office, European standardisation organisations and bodies or experts groups established under relevant sectorial Union law as well as industry, SMEs, start-ups, civil society, researchers and social partners, and should ultimately facilitate global cooperation on standardisation in the field of AI in a manner consistent with Union values. When preparing the standardisation request, the Commission should consult the AI Office and the AI advisory Forum in order to collect relevant expertise.

### **Amendment 105**

Proposal for a regulation Recital 61 b (new)

Text proposed by the Commission

Amendment

(61 b) When AI systems are intended to be used at the workplace, harmonised standards should be limited to technical specifications and procedures.

**Amendment 106** 

Proposal for a regulation Recital 61 c (new)

Text proposed by the Commission

Amendment

(61 c) The Commission should be able to adopt common specifications under certain conditions, when no relevant harmonised standard exists or to address specific fundamental rights concerns. Through the whole drafting process, the Commission should regularly consult the

AI Office and its advisory forum, the European standardisation organisations and bodies or expert groups established under relevant sectorial Union law as well as relevant stakeholders, such as industry, SMEs, start-ups, civil society, researchers and social partners.

### Amendment 107

# Proposal for a regulation Recital 61 d (new)

Text proposed by the Commission

#### Amendment

(61 d) When adopting common specifications, the Commission should strive for regulatory alignment of AI with likeminded global partners, which is key to fostering innovation and cross-border partnerships within the field of AI, as coordination with likeminded partners in international standardisation bodies is of great importance.

### **Amendment 108**

# 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. To increase the trust in the value chain and to give certainty to businesses about the performance of their systems, third-parties that supply AI components may voluntarily apply for a third-party conformity assessment.

### **Amendment 109**

# 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 *complexity of high-risk* AI systems and the risks that are associated to them, it is essential to develop a more adequate capacity for the application of third party conformity assessment for high-risk AI systems. However, given the current 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, or AI systems intended to be used to make inferences about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems for which the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited

### **Amendment 110**

### 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,

### 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

PE731.563v02-00 88/665 RR\1279290EN.docx

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.

authorities, provided they are compliant with a set of requirements, notably on independence, competence, absence of conflicts of interests and minimum cybersecurity requirements. Member States should encourage the designation of a sufficient number of conformity assessment bodies, in order to make the certification feasible in a timely manner. The procedures of assessment, designation, notification and monitoring of conformity assessment bodies should be implemented as uniformly as possible in Member States, with a view to removing administrative border barriers and ensuring that the potential of the internal market is realised.

### **Amendment 111**

Proposal for a regulation Recital 65 a (new)

Text proposed by the Commission

### Amendment

(65 a) In line with Union commitments under the World Trade Organization Agreement on Technical Barriers to Trade, it is adequate to maximise the acceptance of test results produced by competent conformity assessment bodies, independent of the territory in which they are established, where necessary to demonstrate conformity with the applicable requirements of the Regulation. The Commission should actively explore possible international instruments for that purpose and in particular pursue the possible establishment of mutual recognition agreements with countries which are on a comparable level of technical development, and have compatible approach concerning AI and conformity assessment.

### Amendment 112

## Proposal for a regulation Recital 66

Text proposed by the Commission

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 high-risk AI system undergoes a new conformity assessment whenever an unplanned change occurs which goes beyond controlled or predetermined changes by the provider including continuous learning and which may create a new unacceptable risk and significantly affect the compliance of the high-risk AI 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. 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, provided that they do not amount to a substantial modification

### **Amendment 113**

# Proposal for a regulation Recital 67

Text proposed by the Commission

(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that Amendment

(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that

PE731.563v02-00 90/665 RR\1279290EN.docx

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.

they can move freely within the internal market. For physical high-risk AI systems, a physical CE marking should be affixed, and may be complemented by a digital CE marking. For digital only high-risk AI systems, a digital CE marking should be used. 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.

### **Amendment 114**

## 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

(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons, *the environment and climate change* and for society as a whole. It is thus appropriate that under exceptional reasons of protection of life and health of natural persons, *environmental protection* and the protection of *critical infrastructure*, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

### **Amendment 115**

## 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

## 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 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 Council<sup>55</sup>. 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.

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 and foundation models in a EU database, to be established and managed by the Commission. This database should be freely and publicly accessible, easily understandable and machine-readable. The database should also be user-friendly and easily navigable, with search functionalities at minimum allowing the general public to search the database for specific high-risk systems, locations, categories of risk under Annex IV and keywords. Deployers who are public authorities or Union institutions, bodies, offices and agencies or deployers acting on their behalf and deployers who are undertakings designated as a gatekeeper under Regulation (EU)2022/1925 should also register in the EU database before putting into service or using a high-risk AI system for the first time and following each substantial modification. Other deployers should be entitled to do so voluntarily. Any substantial modification of high-risk AI systems shall also be registered in the EU database. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>55</sup>. 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. The Commission should take into account cybersecurity and hazard-related risks when carrying out its tasks as data controller on the EU database. 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 Directive 2019/882.

<sup>55</sup> 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).

<sup>55</sup> 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).

### **Amendment 116**

## Proposal for a regulation Recital 71

Text proposed by the Commission

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

Artificial intelligence is a rapidly developing family of technologies that requires regulatory oversight and a safe and controlled space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that *promotes innovation*, is future-proof, and resilient to disruption, Member States should establish at least one artificial intelligence regulatory sandbox 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. It is indeed desirable for the establishment of regulatory sandboxes, whose establishment is currently left at the discretion of Member States, as a next step to be made mandatory with established criteria. That mandatory sandbox could also be established jointly with one or several other Member States. as long as that sandbox would cover the respective national level of the involved Member States. Additional sandboxes may also be established at different levels, including cross Member States, in order to facilitate cross-border cooperation and

synergies. With the exception of the mandatory sandbox at national level, Member States should also be able to establish virtual or hybrid sandboxes. All regulatory sandboxes should be able to accommodate both physical and virtual products. Establishing authorities should also ensure that the regulatory sandboxes have the adequate financial and human resources for their functioning.

### **Amendment 117**

## 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,

### Amendment

(72)The objectives of the regulatory sandboxes should be: for the establishing authorities to increase their understanding of technical developments, improve supervisory methods and provide guidance to AI systems developers and providers to achieve regulatory compliance with this Regulation or where relevant, other applicable Union and Member States legislation, as well as with the Charter of Fundamental Rights; for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems in the pre-marketing phase to enhance legal certainty, to allow for more regulatory learning by establishing authorities in a controlled environment to develop better guidance and to identify possible future improvements of the legal framework through the ordinary legislative procedure. Any significant risks identified during the development and testing of such AI systems should result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. To ensure uniform implementation across the Union and economies of scale, it is appropriate to

PE731.563v02-00 94/665 RR\1279290EN.docx

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.

establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. *Member* **States** should ensure *that regulatory* sandboxes are widely available throughout the Union, while the participation should remain voluntary. It is especially important to ensure that SMEs and startups can easily access these sandboxes, are actively involved and participate in the development and testing of innovative AI systems, in order to be able to contribute with their knowhow and experience

### **Amendment 118**

Proposal for a regulation Recital 72 a (new)

Text proposed by the Commission

### Amendment

(72 a) 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 only under specified conditions 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. Prospective providers 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, health and the environment and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the prospective providers in the sandbox should be taken into account when competent authorities decide over

the temporary or permanent suspension of their participation in the sandbox whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

### **Amendment 119**

Proposal for a regulation Recital 72 b (new)

Text proposed by the Commission

### Amendment

(72 b) 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 nondiscrimination, accessibility, consumer, environmental, and digital rights, as well as academics

### Amendment 120

# 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.

### 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 *AI literacy*, awareness raising and information

PE731.563v02-00 96/665 RR\1279290EN.docx

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.

communication. Member States shall utilise existing channels and where appropriate, establish new dedicated channels for communication with SMEs, start-ups, user and other innovators to provide guidance and respond to queries about the implementation of this Regulation. 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 other relevant instruments funded by EU programmes as well as the Testing and Experimentation Facilities established by the Commission and the Member States at national or Union level. Where appropriate, these channels shall work together to create synergies and ensure homogeneity in their guidance to startups, SMEs and users. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. The Commission shall regularly assess the certification and compliance costs for SMEs and start-ups, including through transparent consultations with SMEs, start-ups and users and shall work with Member States to lower such costs. *For example,* 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. Medium-sized enterprises which recently changed from the small to medium-size category within the meaning of the Annex to Recommendation 2003/361/EC (Article 16) shall have access to these initiatives and guidance for a period of time deemed

appropriate by the Member States, as these new medium-sized enterprises may sometimes lack the legal resources and training necessary to ensure proper understanding and compliance with provisions.

### **Amendment 121**

### 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 AIon 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 AIon 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.

### **Amendment 122**

## 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

### Amendment

(76) In order to avoid fragmentation, to ensure the optimal functioning of the Single market, to ensure effective and harmonised implementation of this Regulation, to achieve a high level of trustworthiness and of protection of

PE731.563v02-00 98/665 RR\1279290EN.docx

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.

health and safety, fundamental rights, the environment, democracy and the rule of law across the Union with regards to AI systems, to actively support national supervisory authorities, Union institutions, bodies, offices and agencies in matters pertaining to this Regulation, 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, should be responsible for a number of advisory and coordination tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation 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, the FRA, and ENISA. An executive director should be responsible for managing the activities of the secretariat of the AI office and for representing the AI office. Stakeholders should formally participate in the work of the AI Office through an advisory forum that should ensure varied and balanced stakeholder representation and should advise the AI Office on matters pertaining to. In case the establishment of the AI Office prove not to be sufficient to ensure a fully consistent application of this Regulation at Union level as well as efficient cross-border enforcement measures, the creation of an AI agency should be considered.

**Amendment 123** 

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

Each Member State should (77)designate a national supervisory authority for the purpose of supervising the application and implementation of this Regulation. It should also represent its Member State at the management board of the AI Office. 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. *Each* national supervisory authority should act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.

### **Amendment 124**

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 relevant national competent authorities, the Commission, and with the AI Office.

### **Amendment 125**

Proposal for a regulation Recital 77 b (new)

Text proposed by the Commission

Amendment

(77 b) The member or the staff of each

PE731.563v02-00 100/665 RR\1279290EN.docx

national supervisory authority should, in accordance with Union or national law, be subject to a duty of professional secrecy both during and after their term of office, with regard to any confidential information which has come to their knowledge in the course of the performance of their tasks or exercise of their powers. During their term of office, that duty of professional secrecy should in particular apply to trade secrets and to reporting by natural persons of infringements of this Regulation

### **Amendment 126**

## Proposal for a regulation Recital 78

Text proposed by the Commission

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

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' or evolve 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 and take appropriate corrective actions. Deployers should also report to the relevant authorities, any serious incidents or breaches to national and Union law resulting from the use of their AI system when they become aware

#### Amendment 127

# 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 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.

### 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. For the purpose of this Regulation, national supervisory authorities should act as market surveillance authorities for AI systems covered by this Regulation except for AI systems covered by Annex II of this Regulation. For AI systems covered by legal acts listed in the Annex II, the competent authorites under those legal acts should remain the lead authority. National supervisory authorities and competent authorities in the legal acts listed in Annex II should work together whenever necessary. When appropriate, the competent authorities in the legal acts listed in Annex II should send competent staff to the national supervisory authority in order to assist in the performance of its tasks. For the purpose of this Regulation, national supervisory authorities should have the same powers and obligations as market surveillance authorities under Regulation (EU) 2019/1020. 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. After having exhausted all other reasonable ways to assess/verify the conformity and upon a reasoned request,

PE731.563v02-00 102/665 RR\1279290EN.docx

the national supervisory authority should be granted access to the training, validation and testing datasets, the trained and training model of the high-risk AI system, including its relevant model parameters and their execution /run environment. In cases of simpler software systems falling under this Regulation that are not based on trained models, and where all other ways to verify conformity have been exhausted, the national supervisory authority may exceptionally have access to the source code, upon a reasoned request. Where the national supervisory authority has been granted access to the training, validation and testing datasets in accordance with this Regulation, such access should be achieved through appropriate technical means and tools, including on site access and in exceptional circumstances, remote access. The national supervisory authority should treat any information, including source code, software, and data as applicable, obtained as confidential information and respect relevant Union law on the protection of intellectual property and trade secrets. The national supervisory authority should delete any information obtained upon the completion of the investigation.

### **Amendment 128**

# 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

## Amendment

(80) Union *law* 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 Council<sup>56</sup>, 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 129** 

Proposal for a regulation Recital 80 a (new)

relevant rules and requirements of the Union financial services law, the *competent* authorities responsible for the supervision and enforcement of the financial services law, 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 Council<sup>56</sup>, 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 deployers of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

<sup>&</sup>lt;sup>56</sup> 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).

<sup>&</sup>lt;sup>56</sup> 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).

### Amendment

(80 a) Given the objectives of this Regulation, namely to ensure an equivalent level of protection of health, safety and fundamental rights of natural persons, to ensure the protection of the rule of law and democracy, and taking into account that the mitigation of the risks of AI system against such rights may not be sufficiently achieved at national level or may be subject to diverging interpretation which could ultimately lead to an uneven level of protection of natural persons and create market fragmentation, the national supervisory authorities should be empowered to conduct joint investigations or rely on the union safeguard procedure provided for in this Regulation for effective enforcement. Joint investigations should be initiated where the national supervisory authority have sufficient reasons to believe that an infringement of this Regulation amount to a widespread infringement or a widespread infringement with a Union dimension, or where the AI system or foundation model presents a risk which affects or is likely to affect at least 45 million individuals in more than one Member State.

### Amendment 130

## 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

### 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

the European Parliament and of the Council<sup>57</sup> would apply as a safety net.

2001/95/EC of the European Parliament and of the Council<sup>57</sup> would apply as a safety net.

### **Amendment 131**

# 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 while respecting the confidentiality of information and data obtained in carrying out their tasks by putting in place technical and organisational measures to protect the security and confidentiality of the information obtained carrying out their activities including for intellectual property rights and public and national security interests. Where the activities of the Commission, national competent authorities and notified bodies pursuant to this Regulation results in a breach of intellectual property rights, Member States should provide for adequate measures and remedies to ensure the enforcement of intellectual property rights in application of Directive 2004/48/EC.

## **Amendment 132**

Proposal for a regulation Recital 84

PE731.563v02-00 106/665 RR\1279290EN.docx

<sup>&</sup>lt;sup>57</sup> 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).

<sup>&</sup>lt;sup>57</sup> 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).

### 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

Compliance with this Regulation (84)should be enforceable by means of the imposition of fines by the national supervisory authority when carrying out proceedings under the procedure laid down in this Regulation. 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. In order to strengthen and harmonise administrative penalties for infringement of this Regulation, the upper limits for setting the administrative fines for certain specific infringements should be laid down;. When assessing the amount of the fines, national competent authorities should, in each individual case, take 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 to the provider's size, in particular if the provider is a SME or a start-up. 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.

### **Amendment 133**

Proposal for a regulation Recital 84 a (new)

Text proposed by the Commission

Amendment

(84 a) As the rights and freedoms of natural and legal persons and groups of natural persons can be seriously undermined by AI systems, it is essential

that natural and legal persons or groups of natural persons have meaningful access to reporting and redress mechanisms and to be entitled to access proportionate and effective remedies. They should be able to report infringments of this Regulation to their national supervisory authority and have the right to lodge a complaint against the providers or deployers of AI systems. Where applicable, deployers should provide internal complaints mechanisms to be used by natural and legal persons or groups of natural persons. Without prejudice to any other administrative or non-judicial remedy, natural and legal persons and groups of natural persons should also have the right to an effective judicial remedy with regard to a legally binding decision of a national supervisory authority concerning them or, where the national supervisory authority does not handle a complaint, does not inform the complainant of the progress or preliminary outcome of the complaint lodged or does not comply with its obligation to reach a final decision, with regard to the complaint.

### Amendment 134

Proposal for a regulation Recital 84 b (new)

Text proposed by the Commission

Amendment

(84 b) Affected persons should always be informed that they are subject to the use of a high-risk AI system, when deployers use a high-risk AI system to assist in decision-making or make decisions related to natural persons. This information can provide a basis for affected persons to exercise their right to an explanation under this Regulation. When deployers provide an explanation to affected persons under this Regulation, they should take into account

## the level of expertise and knowledge of the average consumer or individual

#### **Amendment 135**

## Proposal for a regulation Recital 84 c (new)

Text proposed by the Commission

#### Amendment

(84 c) Union law 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.

#### **Amendment 136**

## Proposal for a regulation Recital 85

Text proposed by the Commission

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

#### Amendment

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 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

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-Making<sup>58</sup>. 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.

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-Making<sup>58</sup>. These consultations should involve the participation of a balanced selection of stakeholders, including consumer organisations, civil society, 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.

## **Amendment 137**

## Proposal for a regulation Recital 85 a (new)

Text proposed by the Commission

#### Amendment

(85 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 the implementation of this Regulation, in particular the prohibited AI systems, the transparency obligations and the list of high-risk areas and use cases, at least every year, while consulting the AI office and the relevant stakeholders.

#### **Amendment 138**

<sup>&</sup>lt;sup>58</sup> OJ L 123, 12.5.2016, p. 1.

<sup>&</sup>lt;sup>58</sup> OJ L 123, 12.5.2016, p. 1.

## 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 introduce of an adequate methodology to measure the environmental impact and effectiveness of this Regulation in light of the Union environmental and climate objectives.

#### **Amendment 139**

## 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 June 2021.

### **Amendment 140**

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

Text proposed by the Commission

### Amendment

1. The purpose of this Regulation is to promote the uptake of human-centric and trustworthy artificial intelligence and to ensure a high level of protection of health, safety, fundamental rights, democracy and the rule of law, and the environment from harmful effects of

## artificial intelligence systems in the Union while supporting innovation;

#### **Amendment 141**

## 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;

Amendment 142 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 *governance* and *enforcement*;

#### **Amendment 143**

Proposal for a regulation Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

#### Amendment

(e a) measures to support innovation, with a particular focus on SMEs and start-ups, including on setting up regulatory sandboxes and targeted measures to reduce the regulatory burden on SMEs's and start-ups;

#### **Amendment 144**

PE731.563v02-00 112/665 RR\1279290EN.docx

## Proposal for a regulation Article 1 – paragraph 1 – point e b (new)

Text proposed by the Commission

Amendment

(e b) rules for the establishment and functioning of the Union's Artificial Intelligence Office (AI Office).

#### **Amendment 145**

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 *that have their place of establishment or who are* located within the Union;

#### **Amendment 146**

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 deployers of AI systems that have their place of establishment or who are located in a third country, where either Member State law applies by virtue of a public international law or the output produced by the system is intended to be used in the Union;

#### Amendment 147

Proposal for a regulation Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

#### Amendment

(c a) providers placing on the market or putting into service AI systems referred to in Article 5 outside the Union where the

RR\1279290EN.docx 113/665 PE731.563v02-00

## provider or distributor of such systems is located within the Union;

#### **Amendment 148**

Proposal for a regulation Article 2 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) importers and distributors of AI systems as well as authorised representatives of providers of AI systems, where such importers, distributors or authorised representatives have their establishment or are located in the Union;

#### **Amendment 149**

Proposal for a regulation Article 2 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) affected persons as defined in Article 3(8a) that are located in the Union and whose health, safety or fundamental rights are adversely impacted by the use of an AI system that is placed on the market or put into service within the Union.

#### Amendment 150

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 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 *harmonisation legislation listed in Annex II - Section B*, only Article 84 of this Regulation shall apply;

PE731.563v02-00 114/665 RR\1279290EN.docx

#### **Amendment 151**

Proposal for a regulation Article 2 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) Regulation (EC) 300/2008;

deleted

**Amendment 152** 

Proposal for a regulation Article 2 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) Regulation (EU) No 167/2013;

deleted

**Amendment 153** 

Proposal for a regulation Article 2 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) Regulation (EU) No 168/2013;

deleted

**Amendment 154** 

Proposal for a regulation Article 2 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) Directive 2014/90/EU;

deleted

**Amendment 155** 

Proposal for a regulation Article 2 – paragraph 2 – point e Text proposed by the Commission

Amendment

(e) Directive (EU) 2016/797;

deleted

**Amendment 156** 

Proposal for a regulation Article 2 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) Regulation (EU) 2018/858;

deleted

Amendment 157

Proposal for a regulation Article 2 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) Regulation (EU) 2018/1139;

deleted

**Amendment 158** 

Proposal for a regulation Article 2 – paragraph 2 – point h

Text proposed by the Commission

Amendment

(h) Regulation (EU) 2019/2144.

deleted

**Amendment 159** 

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

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

PE731.563v02-00 116/665 RR\1279290EN.docx

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.

organisations use AI systems in the framework of international cooperation or 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 TFUE providing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals:

**Amendment 160** 

Proposal for a regulation Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processes in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulations (EU) 2016/679 and (EU) 2018/1725 and Directives 2002/58/EC and (EU) 2016/680, without prejudice to arrangements provided for in Article 10(5) and Article 54 of this Regulation.;

**Amendment 161** 

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 related to consumer protection and product safety;

#### **Amendment 162**

Proposal for a regulation Article 2 – paragraph 5 c (new)

Text proposed by the Commission

### Amendment

5 c. This regulation shall not preclude Member States or the Union from maintaining or introducing laws, regulations or administrative provisions which are more favourable to workers in terms of protecting their rights in respect of the use of AI systems by employers, or to encourage or allow the application of collective agreements which are more favourable to workers.

#### Amendment 163

Proposal for a regulation Article 2 – paragraph 5 d (new)

Text proposed by the Commission

#### Amendment

5 d. This Regulation shall not apply to research, testing and development activities regarding an AI system prior to this system being placed on the market or put into service, provided that these activities are conducted respecting fundamental rights and the applicable Union law. The testing in real world conditions shall not be covered by this exemption. The Commission is empowered to may adopt delegated acts in accordance with Article 73 that clarify the application of this paragraph to specify this exemption to prevent its existing and potential abuse. The AI Office shall provide guidance on the governance of research and development pursuant to

PE731.563v02-00 118/665 RR\1279290EN.docx

Article 56, also aiming to coordinate its application by the national supervisory authorities;

#### **Amendment 164**

Proposal for a regulation Article 2 – paragraph 5 e (new)

Text proposed by the Commission

#### Amendment

5 e. This Regulation shall not apply to AI components provided under free and open-source licences except to the extent they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV. This exemption shall not apply to foundation models as defined in Art 3.

#### **Amendment 165**

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 is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions, that influence physical or virtual environments;

#### **Amendment 166**

Proposal for a regulation Article 3 – paragraph 1 – point 1 a (new) Text proposed by the Commission

Amendment

(1 a) 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;

**Amendment 167** 

Proposal for a regulation Article 3 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1 b) 'significant risk' means a risk that is significant as a result of the combination of its severity, intensity, probability of occurrence, and duration of its effects, and its the ability to affect an individual, a plurality of persons or to affect a particular group of persons;

**Amendment 168** 

Proposal for a regulation Article 3 – paragraph 1 – point 1 c (new)

Text proposed by the Commission

Amendment

(1 c) 'foundation model' means an AI system model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;

**Amendment 169** 

Proposal for a regulation Article 3 – paragraph 1 – point 1 d (new)

Text proposed by the Commission

Amendment

(1 d) 'general purpose AI system' means an AI system that can be used in and adapted to a wide range of

PE731.563v02-00 120/665 RR\1279290EN.docx

## applications for which it was not intentionally and specifically designed;

#### **Amendment 170**

Proposal for a regulation Article 3 – paragraph 1 – point 1 e (new)

Text proposed by the Commission

Amendment

(1 e) 'large training runs' means the production process of a powerful AI model that require computing resources above a very high threshold;

#### **Amendment 171**

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/EC<sup>61</sup>;

deleted

<sup>61</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

#### **Amendment 172**

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 nonprofessional activity; used in the course of a personal nonprofessional activity;

#### **Amendment 173**

## 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 deployer*, the authorised representative, the importer and the distributor;

## **Amendment 174**

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 otherwise affected by an AI system;

### **Amendment 175**

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;

## **Amendment 176**

Proposal for a regulation Article 3 – paragraph 1 – point 13

PE731.563v02-00 122/665 RR\1279290EN.docx

## 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 *as indicated in instructions for use established by the provider*, but which may result from reasonably foreseeable human behaviour or interaction with other systems, *including other AI systems*;

#### **Amendment 177**

## 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 Union harmonisation law listed in* 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;

#### **Amendment 178**

## 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, *as well as information on any precautions to be taken;* inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

#### **Amendment 179**

## 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 *that has been* made available to *deployers*;

#### **Amendment 180**

## 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;

#### **Amendment 181**

## 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 this Regulation and other relevant Union harmonisation legislation;

## **Amendment 182**

## 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

#### Amendment

(23) 'substantial modification' means a *modification or a series of modifications* 

PE731.563v02-00 124/665 RR\1279290EN.docx

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:

of the AI system after its placing on the market or putting into service which is not foreseen or planned in the initial risk assessment 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 of this Regulation is affected or results in a modification to the intended purpose for which the AI system has been assessed;

### **Amendment 183**

## 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;

#### **Amendment 184**

## 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;

#### **Amendment 185**

## 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;

#### **Amendment 186**

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 biometric data as defined in Article 4, point (14) of Regulation (EU) 2016/679;

## **Amendment 187**

Proposal for a regulation Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

#### Amendment

(33 a) 'biometric-based data' means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person;

#### **Amendment 188**

PE731.563v02-00 126/665 RR\1279290EN.docx

## Proposal for a regulation Article 3 – paragraph 1 – point 33 b (new)

Text proposed by the Commission

Amendment

(33 b) 'biometric identification' means the automated recognition of physical, physiological, behavioural, and psychological human features for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification);

#### **Amendment 189**

Proposal for a regulation Article 3 – paragraph 1 – point 33 c (new)

Text proposed by the Commission

Amendment

(33 c) 'biometric verification' means the automated verification of the identity of natural persons by comparing biometric data of an individual to previously provided biometric data (one-to-one verification, including authentication);

#### **Amendment 190**

Proposal for a regulation Article 3 – paragraph 1 – point 33 d (new)

Text proposed by the Commission

Amendment

(33 d) 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU)2016/679;

## **Amendment 191**

## 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:

#### **Amendment 192**

## 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 means assigning natural persons to specific categories, *or inferring their characteristics and attributes* on the basis of their biometric *or biometric-based* data, *or which can be inferred from such data*;

#### Amendment 193

## 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 *deployer* of the AI system whether the person will be present and can be identified, *excluding verification systems*;

PE731.563v02-00 128/665 RR\1279290EN.docx

#### Amendment 194

## 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) "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 delays in order to avoid circumvention;

#### **Amendment 195**

## 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 the public, regardless of whether certain conditions for access may apply, *and regardless of the potential capacity restrictions*;

# Amendment 196 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;

#### Amendment 197

## 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 *a public (AM 69)* 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 198**

## Proposal for a regulation Article 3 – paragraph 1 – point 43

Text proposed by the Commission

(43) 'national competent authority' means the national *supervisory authority*, the notifying authority and the market surveillance authority;

#### Amendment

(43) 'national competent authority' means any of the national authorities which are responsible for the enforcement of this Regulation;

#### **Amendment 199**

## 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 *or malfunctioning of an AI system* that directly or indirectly leads, might have led or might lead to any of the following:
- (a) the death of a person or serious damage to a person's health,
- (b) a serious disruption of the management and operation of critical

PE731.563v02-00 130/665 RR\1279290EN.docx

#### infrastructure;

- (b a) a breach of fundamental rights protected under Union law;
- (b b) serious damage to property or the environment;

#### **Amendment 200**

Proposal for a regulation Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44 a) 'personal data' means personal data as defined in Article 4, point (1) of Regulation (EU)2016/679;

#### **Amendment 201**

Proposal for a regulation Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) 'non-personal data' means data other than personal data;

### **Amendment 202**

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 in point (4) of Article 4 of Regulation (EU) 2016/679; or in the case of law enforcement authorities – in point 4 of Article 3 of Directive (EU) 2016/680 or, in the case of Union institutions, bodies, offices or agencies, in point 5 Article 3 of Regulation (EU) 2018/1725;

#### Amendment 203

Proposal for a regulation Article 3 – paragraph 1 – point 44 d (new)

Text proposed by the Commission

Amendment

(44 d) "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, produced using AI techniques, including machine learning and deep learning;

#### **Amendment 204**

Proposal for a regulation Article 3 – paragraph 1 – point 44 e (new)

Text proposed by the Commission

#### Amendment

- (44 e) 'widespread infringement' means any act or omission contrary to Union law that protects the interest of individuals:
- (a) which has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State, in which:
- (i) the act or omission originated or took place;
- (ii) the provider concerned, or, where applicable, its authorised representative is established; or,
- (iii) the deployer is established, when the infringement is committed by the deployer;
- (b) which protects the interests of individuals, that have caused, cause or are likely to cause harm to the collective interests of individuals and that have common features, including the same unlawful practice, the same interest being infringed and that are occurring

PE731.563v02-00 132/665 RR\1279290EN.docx

concurrently, committed by the same operator, in at least three Member States;

**Amendment 205** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 f (new)

Text proposed by the Commission

Amendment

(44 f) 'widespread infringement with a Union dimension' means a widespread infringement that has harmed or is likely to harm the collective interests of individuals in at least two-thirds of the Member States, accounting, together, for at least two-thirds of the population of the Union;

**Amendment 206** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 g (new)

Text proposed by the Commission

Amendment

(44 g) 'regulatory sandbox' means a controlled environment established by a public authority 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 under regulatory supervision;

**Amendment 207** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 h (new)

Text proposed by the Commission

Amendment

(44 h) 'critical infrastructure' means an asset, a facility, equipment, a network or a system, or a part of an asset, a facility,

equipment, a network or a system, which is necessary for the provision of an essential service within the meaning of Article 2(4) of Directive (EU) 2022/2557;

#### **Amendment 208**

Proposal for a regulation Article 3 – paragraph 1 – point 44 k (new)

Text proposed by the Commission

Amendment

(44 k) 'social scoring' means evaluating or classifying natural persons based on their social behaviour, socio-economic status or known or predicted personal or personality characteristics;

**Amendment 209** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 l (new)

Text proposed by the Commission

Amendment

(44 l) 'social behaviour' means the way a natural person interacts with and influences other natural persons or society;

**Amendment 210** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 m (new)

Text proposed by the Commission

Amendment

(44 m) 'state of the art' means the developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience;

#### Amendment 211

Proposal for a regulation Article 3 – paragraph 1 – point 44 n (new)

Text proposed by the Commission

Amendment

(44 n) 'testing in real world conditions' means the temporary testing of an AI system for its intended purpose in real world conditions outside of a laboratory or otherwise simulated environment;

**Amendment 212** 

Proposal for a regulation Article 4

Text proposed by the Commission

Amendment

deleted

Article 4

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.

**Amendment 213** 

Proposal for a regulation Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

General principles applicable to all AI systems

1. All operators falling under this Regulation shall make their best efforts to develop and use AI systems or foundation models in accordance with the following

- general principles establishing a highlevel framework that promotes a coherent human-centric European approach to ethical and trustworthy Artificial Intelligence, which is fully in line with the Charter as well as the values on which the Union is founded:
- a) '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 appropriately controlled and overseen by humans;
- b) '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 unintended problems
  and being resilient against attempts to
  alter the use or performance of the AI
  system so as to allow unlawful use by
  malicious third parties;
- c) '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;
- d) '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 and affected persons about their rights;
- e) '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, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national law;

- f) '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.
- 2. Paragraph 1 is without prejudice to obligations set up by existing Union and national law. For high-risk AI systems, the general principles are translated into and complied with by providers or deployers by means of the requirements set out in Articles 8 to 15, and the relevant obligations laid down in Chapter 3 of Title III of this Regulation. For foundation models, the general principles are translated into and complied with by providers by means of the requirements set out in Articles 28 to 28b. For all AI systems, the application of the principles referred to in paragraph 1 can be achieved, as applicable, through the provisions of Article 28, Article 52, or the application of harmonised standards, technical specifications, and codes of conduct as referred to in Article 69, without creating new obligations under this Regulation.
- 3. The Commission and the AI Office shall incorporate these guiding principles in standardisation requests as well as recommendations consisting in technical guidance to assist providers and deployers on how to develop and use AI systems. European Standardisation Organisations shall take the general principles referred to in paragraph 1 of this Article into account as outcome-based objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b).

**Amendment 214** 

## Proposal for a regulation Article 4 b (new)

Text proposed by the Commission

Amendment

#### Article 4 b

## AI literacy

- 1. When implementing this Regulation, the Union and the Member States shall promote measures for the development of a sufficient level of AI literacy, across sectors and taking into account the different needs of groups of providers, deployers and affected persons concerned, including through education and training, skilling and reskilling programmes and while ensuring proper gender and age balance, in view of allowing a democratic control of AI systems
- 2. Providers and deployers of AI systems shall take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on which the AI systems are to be used.
- 3. Such literacy measures shall consist, in particular, of the teaching of basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits.
- 4. A sufficient level of AI literacy is one that contributes, as necessary, to the ability of providers and deployers to ensure compliance and enforcement of this Regulation.

**Amendment 215** 

PE731.563v02-00 138/665 RR\1279290EN.docx

## 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

the placing on the market, putting (a) into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective to or the effect of materially distorting a person's or a group of persons' behaviour by appreciably impairing the person's ability to make an informed decision, thereby causing the person to take a decision that that person would not have otherwise taken in a manner that causes or is likely to cause that person, another person or group of persons significant harm;

The prohibition of AI system that deploys subliminal techniques referred to in the first sub-paragraph shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian;

#### **Amendment 216**

## 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 specific group of persons, including characteristics of such person's or a such group's known or predicted personality traits or social or economic situation age, physical or mental ability with the objective or to the effect of materially distorting the behaviour of that person or a person pertaining to that group

in a manner that causes or is likely to cause that person or another person *significant* harm;

#### **Amendment 217**

## Proposal for a regulation Article 5 – paragraph 1 – point b a (new)

Text proposed by the Commission

#### Amendment

(b a) the placing on the market, putting into service or use of biometric categorisation systems that categorise natural persons according to sensitive or protected attributes or characteristics or based on the inference of those attributes or characteristics. This prohibition shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.

#### **Amendment 218**

## 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 *social scoring* evaluation or classification of natural persons *or groups thereof* over a certain period of time based on their social behaviour or known, *inferred* or predicted personal or personality characteristics, with the social score leading to either or both of the following:

#### **Amendment 219**

PE731.563v02-00 140/665 RR\1279290EN.docx

## 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;

#### **Amendment 220**

## 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;

### **Amendment 221**

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 222**

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

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substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack;

#### **Amendment 223**

Proposal for a regulation Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

deleted

(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/JHA<sup>62</sup> 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).

#### **Amendment 224**

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 making risk assessments of natural persons or groups thereof 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 or administrative offence based on profiling

PE731.563v02-00 142/665 RR\1279290EN.docx

of a natural person or on assessing personality traits and characteristics, including the person's location, or past criminal behaviour of natural persons or groups of natural persons;

**Amendment 225** 

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 that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;

**Amendment 226** 

Proposal for a regulation Article 5 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

dc) the placing on the market, putting into service or use of AI systems to infer emotions of a natural person in the areas of law enforcement, border management, in workplace and education institutions.

**Amendment 227** 

Proposal for a regulation Article 5 – paragraph 1 – point d d (new)

Text proposed by the Commission

Amendment

(d d) the putting into service or use of AI systems for the analysis of recorded footage of publicly accessible spaces through 'post' remote biometric identification systems, unless they are

subject to a pre-judicial authorisation in accordance with Union law and strictly necessary for the targeted search connected to a specific serious criminal offense as defined in Article 83(1) of TFEU that already took place for the purpose of law enforcement.

#### **Amendment 228**

Proposal for a regulation Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. This Article shall not affect the prohibitions that apply where an artificial intelligence practice infringes another Union law, including Union law on data protection, non discrimination, consumer protection or competition;

Amendment

#### **Amendment 229**

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

- deleted
- 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

PE731.563v02-00 144/665 RR\1279290EN.docx

# 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.

## **Amendment 230**

Proposal for a regulation Article 5 – paragraph 3

Text proposed by the Commission

deleted

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 'realtime' 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.

# **Amendment 231**

# 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

deleted

## **Amendment 232**

# 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 the AI system* is itself a product, covered by the Union harmonisation *law* listed in Annex II;

PE731.563v02-00 146/665 RR\1279290EN.docx

# 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 234**

# 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

(b) the product whose safety component *pursuant to point (a)* is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment *related to risks for health and safety*, with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation *law* listed in Annex II;

## Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems falling under one or more of the critical areas and use cases referred to in Annex III shall be considered high-risk if they pose a significant risk of harm to the health, safety or fundamental rights of natural persons. Where an AI system falls under Annex III point 2, it shall be considered to be high-risk if it poses a significant risk of harm to the environment.

The Commission shall, six months prior to the entry into force of this Regulation, after consulting the AI Office and relevant stakeholders, provide guidelines clearly specifying the circumstances where the output of AI systems referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons or cases in which it would not.

Proposal for a regulation Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Where providers falling under one or more of the critical areas and use cases referred to in Annex III consider that their AI system does not pose a significant risk as described in paragraph 2, they shall submit a reasoned notification to the national supervisory authority that they are not subject to the requirements of Title III Chapter 2 of this Regulation. Where the AI system is intended to be used in two or more Member States, that notification shall be addressed to the AI Office. Without prejudice to Article 65, the national supervisory authority shall review and reply to the notification, directly or via the AI Office, within three months if they deem the AI system to be misclassified.

# **Amendment 236**

Proposal for a regulation Article 6 – paragraph 2 a (new)

Text proposed by the Commission

#### Amendment

2 b. Providers that misclassify their AI system as not subject to the requirements of Title III Chapter 2 of this Regulation and place it on the market before the deadline for objection by national supervisory authorities shall be subject to fines pursuant to Article 71.

**Amendment 237** 

PE731.563v02-00 148/665 RR\1279290EN.docx

# Proposal for a regulation Article 6 – paragraph 2 b (new)

Text proposed by the Commission

#### Amendment

2 c. National supervisory authorities shall submit a yearly report to the AI Office detailing the number of notifications received, the related high-risk areas at stake and the decisions taken concerning received notifications

## **Amendment 238**

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 amend Annex III by adding or modifying areas or use-cases of highrisk AI systems where these pose a significant risk of harm to health and safety, or an adverse impact on fundamental rights, to the environment, or to democracy and the rule of law, 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 already referred to in Annex III.

## **Amendment 239**

Proposal for a regulation Article 7 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;

Amendment

deleted

Proposal for a regulation Article 7 – paragraph 1 – point b

Text proposed by the Commission

deleted

(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 241**

Proposal for a regulation Article 7 – paragraph 1 a (new)

Text proposed by the Commission

## Amendment

Amendment

1 a. The Commission is also empowered to adopt delegated acts in accordance with Article 73 to remove usecases of high-risk AI systems from the list in Annex III if the conditions referred to in paragraph 1 no longer apply;

# **Amendment 242**

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 *an AI system* for the purposes of paragraph 1 *and 1a* the Commission shall take into account the following criteria:

PE731.563v02-00 150/665 RR\1279290EN.docx

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;

# Amendment 244

Proposal for a regulation Article 7 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the nature and amount of the data processed and used by the AI system;

## Amendment 245

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 acts autonomously;

## **Amendment 246**

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

## Amendment

(c) the extent to which the use of an AI system has already caused harm to health and safety, *has had an* adverse impact on fundamental rights, *the environment*, *democracy and the rule of law* or has

*materialisation* of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national *competent* authorities;

given rise to significant concerns in relation to the *likelihood* of such harm or adverse impact, as demonstrated *for example* by reports or documented allegations submitted to national *supervisory* authorities, *to the Commission*, *to the AI Office*, *to the EDPS*, *or to the European Union Agency for Fundamental Rights*;

# **Amendment 247**

# 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 to disproportionately affect a particular group of persons;

# **Amendment 248**

# 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 *output* produced *involving* an AI system, *and that output is purely accessory in respect of the relevant action or decision to be taken*, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that *output*;

# **Amendment 249**

Proposal for a regulation Article 7 – paragraph 2 – point e a (new)

PE731.563v02-00 152/665 RR\1279290EN.docx

# Text proposed by the Commission

## Amendment

(e a) the potential misuse and malicious use of the AI system and of the technology underpinning it;

# **Amendment 250**

# Proposal for a regulation Article 7 – paragraph 2 – point f

Text proposed by the Commission

(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;

# Amendment

(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 user of an AI system, in particular due to *status, authority*, knowledge, economic or social circumstances, or age;

## **Amendment 251**

# 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 *or remedied*, whereby outcomes having an *adverse* impact on health, safety, *fundamental rights* of persons, *the environment*, *or on democracy and rule of law* shall not be considered as easily reversible;

# **Amendment 252**

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 effective technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;

# **Amendment 253**

Proposal for a regulation Article 7 – paragraph 2 – point g b (new)

Text proposed by the Commission

Amendment

(g b) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;

# **Amendment 254**

Proposal for a regulation Article 7 – paragraph 2 – point g c (new)

Text proposed by the Commission

Amendment

(g c) 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;

# **Amendment 255**

Proposal for a regulation Article 7 – paragraph 2 – point h –

Text proposed by the Commission

Amendment

- (i) effective measures of redress in relation to the *risks posed* by an AI system, with the exclusion of claims for damages;
- (h) the extent to which existing Union law provides for:

PE731.563v02-00 154/665 RR\1279290EN.docx

- (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;
- (ii) effective measures to prevent or substantially minimise those risks.

Proposal for a regulation Article 7 – paragraph 2 a (new)

Text proposed by the Commission

## Amendment

2 a. When assessing an AI system for the purposes of paragraphs 1 or 1a the Commission shall consult the AI Office and, where relevant, representatives of groups on which an AI system has an impact, industry, independent experts, the social partners, and civil society organisations. The Commission shall also organise public consultations in this regard and shall make the results of those consultations and of the final assessment publicly available;

# **Amendment 257**

Proposal for a regulation Article 7 – paragraph 2 b (new)

Text proposed by the Commission

## Amendment

2 b. The AI Office, national supervisory authorities or the European Parliament may request the Commission to reassess and recategorise the risk categorisation of an AI systemin accordance with paragraphs 1 and 1a. The Commission shall give reasons for its decision and make them public.

# **Amendment 258**

# Proposal for a regulation Article 8 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

1 a. In complying with the requirement established in this Chapter, due account shall be taken of guidelines developed as referred to in Article 82b, the generally acknowledged state of the art, including as reflected in the relevant harmonised standards and common specifications as referred to in articles 40 and 41 or those already set out in Union harmonisation law;.

### **Amendment 259**

# Proposal for a regulation Article 8 – paragraph 2

*Text proposed by the Commission* 

2. The intended purpose of the highrisk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

# **Amendment 260**

Proposal for a regulation Article 8 – paragraph 2 a (new)

Text proposed by the Commission

## Amendment

2. The intended purpose of the high-risk AI system, *the reasonably foreseeable misuses* and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

# Amendment

2 a. As long as the requirements of Title III, Chapters 2 and 3 or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems are addressed by Union harmonisation law listed in Annex II, Section A, the requirements or obligations of those Chapters of this Regulation shall be deemed to be fulfilled, as long as they include the AI component. Requirements

PE731.563v02-00 156/665 RR\1279290EN.docx

of Chapters 2 and 3 of Title III or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems not addressed by Union harmonisation law listed in Annex II Section A, shall be incorporated into that Union harmonisation law, where applicable. The relevant conformity assessment shall be carried out as part of the procedures laid out under Union harmonisation law listed in Annex II, Section A.

#### Amendment 261

# 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. The risk management system can be integrated into, or a part of, already existing risk management procedures relating to the relevant Union sectoral law insofar as it fulfils the requirements of this article.

# **Amendment 262**

# 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 review and updating of the risk management process, to ensure its continuing effectiveness, and documentation of any significant decisions and actions taken subject to this

*Article*. It shall comprise the following steps:

# **Amendment 263**

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, estimation and evaluation of the known and the reasonably foreseeable risks that the highrisk AI system can pose to the health or safety of natural persons, their fundamental rights including equal access and opportunities, democracy and rule of law or the environement when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

# **Amendment 264**

Proposal for a regulation Article 9 – paragraph 2 – point b

Text proposed by the Commission

Amendment

deleted

(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 265**

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

Amendment

(c) evaluation of *emerging significant* risks *as described in point (a) and* 

PE731.563v02-00 158/665 RR\1279290EN.docx

from the post-market monitoring system referred to in Article 61;

*identified* based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

## **Amendment 266**

# 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 designed to address the risks identified pursuant to points a and b of this paragraph in accordance with the provisions of the following paragraphs

# Amendment 267

# 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, with a view to mitigate risks effectively while ensuring an appropriate and proportionate implementation of the requirements.

# **Amendment 268**

# 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

# Amendment

4. The risk management measures referred to in paragraph 2, point *(d)* shall

RR\1279290EN.docx 159/665 PE731.563v02-00

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*.

be such that *relevant* residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is *reasonably* judged *to be* 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*.

In identifying the most appropriate risk management measures, the following shall be ensured:

## **Amendment 269**

# 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* risks as far as *technically feasible* through adequate design and development *of the high-risk AI system, involving when relevant, experts and external stakeholders*;

# **Amendment 270**

# Proposal for a regulation Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

(b) where appropriate, implementation of adequate mitigation and control measures *in relation to* risks that cannot be eliminated;

Amendment

(b) where appropriate, implementation of adequate mitigation and control measures *addressing significant* risks that cannot be eliminated;

# **Amendment 271**

Proposal for a regulation Article 9 – paragraph 4 – subparagraph 1 – point c

PE731.563v02-00 160/665 RR\1279290EN.docx

# 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 *the required* information pursuant to Article 13, and, where appropriate, training to *deployers*.

## **Amendment 272**

# 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 eliminating or reducing risks related to the use of the high-risk AI system, providers shall take into due consideration the technical knowledge, experience, education and training the deployer may need, including in relation to the presumable context of use.

## **Amendment 273**

# 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 and targeted risk management measures and weighing any such measures against the potential benefits and intended goals of the system. 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 274**

# 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. Testing procedures shall be suitable to achieve the intended purpose of the AI system.

# **Amendment 275**

# 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, prior to the placing on the market or the putting into service. Testing shall be made against *prior* defined metrics, and probabilistic thresholds that are appropriate to the intended purpose *or reasonably foreseeable misuse* of the high-risk AI system.

# **Amendment 276**

# 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, *providers shall give* specific consideration to whether the highrisk AI system is likely to *adversely* impact *vulnerable groups of people or* children.

# **Amendment 277**

# 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, including credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of or combined with the risk management procedures established by that Union law.

# **Amendment 278**

# 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 as far as this is technically feasible according to the specific market segment or scope of application.

Techniques that do not require labelled input data such as unsupervised learning and reinforcement learning shall be developed on the basis of data sets such as for testing and verification that meet the quality criteria referred to in paragraphs 2 to 5.

# **Amendment 279**

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 appropriate for the context of use as well as the intended purpose of the AI system. Those measures shall concern in particular,

# **Amendment 280**

Proposal for a regulation Article 10 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) transparency as regards the original purpose of data collection;

# **Amendment 281**

Proposal for a regulation Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) data collection;

(b) data collection *processes*;

## **Amendment 282**

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, *updating* enrichment and aggregation;

## Amendment 283

PE731.563v02-00 164/665 RR\1279290EN.docx

# 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 assumptions, notably with respect to the information that the data are supposed to measure and represent;

# **Amendment 284**

# 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

(e) **an** assessment of the availability, quantity and suitability of the data sets that are needed;

# **Amendment 285**

# 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 health and safety of persons, negatively impact fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations ('feedback loops') and appropriate measures to detect, prevent and mitigate possible biases;

# **Amendment 286**

Proposal for a regulation Article 10 – paragraph 2 – point f a (new)

# (f a) appropriate measures to detect, prevent and mitigate possible biases

## **Amendment 287**

# 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* data gaps or shortcomings *that prevent compliance with this Regulation*, and how those gaps and shortcomings can be addressed;

## **Amendment 288**

# 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 they are used, validation and testing datasets, including the labels, shall be relevant, sufficiently representative, appropriately vetted for errors and be as complete as possible in view of the intended purpose. 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 is intended to be used. These characteristics of the datasets shall be met at the level of individual datasets or a combination thereof.

# **Amendment 289**

Proposal for a regulation Article 10 – paragraph 4

PE731.563v02-00 166/665 RR\1279290EN.docx

# 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 290**

# 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 privacypreserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose *pursued*.

## Amendment

4. **Datasets** shall take into account, to the extent required by the intended purpose **or reasonably foreseeable misuses of the AI system**, the characteristics or elements that are particular to the specific geographical, **contextual** behavioural or functional setting within which the highrisk AI system is intended to be used.

#### Amendment

- 5. To the extent that it is strictly necessary for the purposes of ensuring negative bias detection and correction in relation to the high-risk AI systems, the providers of such systems may exceptionally 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 reuse and use of state-of-the-art security and privacy-preserving. In particular, all the following conditions shall apply in order for this processing to occur: (a) the bias detection and correction cannot be effectively fulfilled by processing synthetic or anonymised data;
- (b) the data are pseudonymised;
- (c) the provider takes appropriate technical and organisational measures to ensure that the data processed for the purpose of this paragraph are secured, protected, subject to suitable safeguards and only authorised persons have access to those data with appropriate

# confidentiality obligations;

- (d) the data processed for the purpose of this paragraph are not to be transmitted, transferred or otherwise accessed by other parties;
- (e) the data processed for the purpose of this paragraph are protected by means of appropriate technical and organisational measures and deleted once the bias has been corrected or the personal data has reached the end of its retention period;
- (f) effective and appropriate measures are in place to ensure availability, security and resilience of processing systems and services against technical or physical incidents:
- (g) effective and appropriate measures are in place to ensure physical security of locations where the data are stored and processed, internal IT and IT security governance and management, certification of processes and products;

Providers having recourse to this provision shall draw up documentation explaining why the processing of special categories of personal data was necessary to detect and correct biases.

# **Amendment 291**

Proposal for a regulation Article 10 – paragraph 6 a (new)

Text proposed by the Commission

# Amendment

6 a. Where the provider cannot comply with the obligations laid down in this Article because that provider does not have access to the data and the data is held exclusively by the deployer, the deployer may, on the basis of a contract, be made responsible for any infringement of this Article.

PE731.563v02-00 168/665 RR\1279290EN.docx

# 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 *supervisory* 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*, *in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority*.

# **Amendment 293**

# 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.

# **Amendment 294**

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.

## Amendment 295

# 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 296**

# 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

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.

# Amendment

- 2. In order to ensure a level of traceability of the AI system's functioning throughout its entire lifetime that is appropriate to the intended purpose of the system, the logging capabilities shall facilitate the monitoring of operations as referred to in Article 29(4) as well as the post market monitoring referred to in Article 61. In particular, they shall enable the recording of events relevant for the identification of situations that may:
- (a) result in the AI system presenting a risk within the meaning of Article65(1); or

PE731.563v02-00 170/665 RR\1279290EN.docx

(b) lead to a substantial modification of the AI system.

**Amendment 297** 

Proposal for a regulation Article 12 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. High-risk AI systems shall be designed and developed with, the logging capabilities enabling the recording of energy consumption, the measurement or calculation of resource use and environmental impact of the high-risk AI system during all phases of the system's lifecycle.

**Amendment 298** 

Proposal for a regulation Article 12 – paragraph 3

Text proposed by the Commission

Amendment

deleted

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 postmarket monitoring referred to in Article 61.

Amendment 299

Proposal for a regulation Article 13 – title

Text proposed by the Commission

Amendment

Transparency and provision of information

Transparency and provision of information

RR\1279290EN.docx 171/665 PE731.563v02-00

# 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 *providers and* users to *reasonably understand* the system's *functioning*. Appropriate transparency shall be ensured *in accordance with the intended purpose of the AI system*, with a view to achieving compliance with the relevant obligations of the provider *and user* set out in Chapter 3 of this Title.

Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall be enabled to understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, allowing the user to explain the decisions taken by the AI system to the affected person pursuant to Article 68(c).

# **Amendment 301**

# 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* 

# Amendment

2. High-risk AI systems shall be accompanied by *intelligible* instructions for use in an appropriate digital format or *made* otherwise *available in a durable* 

PE731.563v02-00 172/665 RR\1279290EN.docx

*clear* information that *is* relevant, accessible and comprehensible to users.

medium that include concise, correct, clear and to the extent possible complete information that helps operating and maintaining the AI system as well as supporting informed decision-making by users and is reasonably relevant, accessible and comprehensible to users.

## Amendment 302

# 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 achieve the outcomes referred to in paragraph 1, information referred to in paragraph 2 shall specify:

## **Amendment 303**

# 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 and, where applicable, of its authorised *representatives*;

# **Amendment 304**

Proposal for a regulation Article 13 – paragraph 3 – point a a (new)

*Text proposed by the Commission* 

# Amendment

(aa) where it is not the same as the provider, the identity and the contact details of the entity that carried out the conformity assessment and, where applicable, of its authorised representative;

# 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 characteristics, capabilities and limitations of performance of the high-risk AI system, including, *where appropriate*:

# **Amendment 306**

# 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 *clearly* known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

# **Amendment 307**

# 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 clearly 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, fundamental rights or the environment, including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used;

PE731.563v02-00 174/665 RR\1279290EN.docx

# Proposal for a regulation Article 13 – paragraph 3 – point b – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) the degree to which the AI system can provide an explanation for decisions it takes;

# **Amendment 309**

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.

# **Amendment 310**

Proposal for a regulation Article 13 – paragraph 3 – point e

Text proposed by the Commission

(e) the expected lifetime of the highrisk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.

# Amendment

(e) any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates, *through its expected lifetime*.

# Amendment 311

Proposal for a regulation Article 13 – paragraph 3 – point e a (new)

# Text proposed by the Commission

## Amendment

(ea) a description of the mechanisms included within the AI system that allows users to properly collect, store and interpret the logs in accordance with Article 12(1).

# **Amendment 312**

Proposal for a regulation Article 13 – paragraph 3 – point e b (new)

Text proposed by the Commission

Amendment

(eb) The information shall be provided at least in the language of the country where the AI system is used.

# **Amendment 313**

Proposal for a regulation Article 13 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in line with Article 4b.

# **Amendment 314**

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

# Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they be effectively overseen by natural persons *as* 

PE731.563v02-00 176/665 RR\1279290EN.docx

period in which the AI system is in use.

proportionate to the risks associated with those systems. Natural persons in charge of ensuring human oversight shall have sufficient level of AI literacy in accordance with Article 4b and the necessary support and authority to exercise that function, during the period in which the AI system is in use and to allow for thorough investigation after an incident.

## **Amendment 315**

# 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, fundamental rights *or environment* 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 and where decisions based solely on automated processing by AI systems produce legal or otherwise significant effects on the persons or groups of persons on which the system is to be used.

# **Amendment 316**

# 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 take into account 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:

# 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 natural persons to whom human oversight is assigned are enabled, as appropriate and proportionate to the circumstances:

#### Amendment 318

# 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) be aware of 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;

#### Amendment 319

# 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, the system through a "stop" button or a similar procedure that allows the system to come to a halt in a safe state, except if the human interference increases the risks or would negatively impact the performance in consideration

PE731.563v02-00 178/665 RR\1279290EN.docx

of generally acknowledged state-of-theart.

## Amendment 320

# 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 point1(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 with the necessary competence, training and authority.

#### **Amendment 321**

# 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 following the principle of security by design and by default. In the light of their intended purpose, they should achieve an appropriate level of accuracy, robustness, safety, and cybersecurity, and perform consistently in those respects throughout their lifecycle. Compliance with these requirements shall include implementation of state-of-the-art measures, according to the specific market segment or scope of application.

## **Amendment 322**

# 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 set out in paragraph 1 of this Article, the AI Office shall bring together national and international metrology and benchmarking authorities and provide non-binding guidance on the matter as set out in Article 56, paragraph 2, point (a).

# **Amendment 323**

Proposal for a regulation Article 15 – paragraph 1 b (new)

Text proposed by the Commission

# Amendment

1b. To address any emerging issues across the internal market with regard to cybersecurity, the European Union Agency for Cybersecurity (ENISA) shall be involved alongside the European Artificial Intelligence Board as set out Article 56, paragraph 2, point (b).

# **Amendment 324**

# 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 declared in the accompanying instructions of use. The language used shall be clear, free of misunderstandings or misleading statements.

PE731.563v02-00 180/665 RR\1279290EN.docx

## Proposal for a regulation Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Technical and organisational measures shall be taken to ensure that high-risk AI systems shall be as resilient as possible regarding 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 326**

## Proposal for a regulation Article 15 – paragraph 3 – subparagraph 2

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 by the appropriate provider with input from the user, where necessary, through technical redundancy solutions, which may include backup or fail-safe plans.

#### **Amendment 327**

## Proposal for a regulation Article 15 – paragraph 3 – subparagraph 3

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') *and malicious manipulation of inputs used in learning during operation* are duly addressed with appropriate mitigation measures.

## Proposal for a regulation Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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.

#### Amendment

High-risk AI systems shall be resilient as regards *to* attempts by unauthorised third parties to alter their use, *behaviour*, *outputs* or performance by exploiting the system vulnerabilities.

#### **Amendment 329**

## Proposal for a regulation Article 15 – paragraph 4 – subparagraph 3

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 to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training dataset ('data poisoning'), or pre-trained components used in training ('model poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples' or 'model evasion'), confidentiality attacks or model flaws, which could lead to harmful decision-making.

#### **Amendment 330**

Proposal for a regulation Title III – Chapter 3 – title

Text proposed by the Commission

OBLIGATIONS OF PROVIDERS AND *USERS* OF HIGH-RISK AI SYSTEMS *and other parties* 

Amendment

OBLIGATIONS OF PROVIDERS AND **DEPLOYERS** OF HIGH-RISK AI SYSTEMS **AND OTHER PARTIES** 

PE731.563v02-00 182/665 RR\1279290EN.docx

# 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 *and other parties* 

## **Amendment 332**

## 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*;

## **Amendment 333**

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 and contact information on the high-risk AI system or, where that is not possible, on its accompanying documentation, as appropriate;

#### **Amendment 334**

Proposal for a regulation Article 16 – paragraph 1 – point a b (new)

#### Amendment

(a b) ensure that natural persons to whom human oversight of high-risk AI systems is assigned are specifically made aware of the risk of automation or confirmation bias;

#### **Amendment 335**

Proposal for a regulation Article 16 – paragraph 1 – point a c (new)

Text proposed by the Commission

#### Amendment

(a c) provide specifications for the input data, or any other relevant information in terms of the datasets used, including their limitation and assumptions, taking into account the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system;

#### **Amendment 336**

## 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) draw-up *and keep* the technical documentation of the high-risk AI system *referred to in Article 11*;

#### **Amendment 337**

## 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 highrisk AI systems;

#### Amendment

(d) when under their control, keep the logs automatically generated by their highrisk AI systems *that are required for* 

PE731.563v02-00 184/665 RR\1279290EN.docx

ensuring and demonstrating compliance with this Regulation, in accordance with Article 20:

#### **Amendment 338**

## 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, *in accordance with Article 43*;

#### **Amendment 339**

Proposal for a regulation Article 16 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) draw up an EU declaration of conformity in accordance with Article 48;

#### **Amendment 340**

Proposal for a regulation Article 16 – paragraph 1 – point e b (new)

Text proposed by the Commission

Amendment

(e b) affix the CE marking to the highrisk AI system to indicate conformity with this Regulation, in accordance with Article 49;

#### **Amendment 341**

Proposal for a regulation Article 16 – paragraph 1 – point g

RR\1279290EN.docx 185/665 PE731.563v02-00

### Amendment

- (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;
- take the necessary corrective (g) actions as referred to in Article 21 and provide information in that regard;

#### Amendment 342

Proposal for a regulation Article 16 - paragraph 1 - point h

Text proposed by the Commission

Amendment

(h) inform the national competent authorities of the Member States in which 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;

deleted

deleted

#### Amendment 343

Proposal for a regulation Article 16 – paragraph 1 – point i

*Text proposed by the Commission* 

Amendment

to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;

#### **Amendment 344**

Proposal for a regulation Article 16 – paragraph 1 – point j

Text proposed by the Commission

upon request of a national (j) competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of

#### Amendment

upon *a reasoned* request of a national supervisory authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2

186/665 RR\1279290EN.docx PE731.563v02-00

this Title. of this Title.

#### **Amendment 345**

Proposal for a regulation Article 16 – paragraph 1 – point j a (new)

Text proposed by the Commission

Amendment

(j a) ensure that the high-risk AI system complies with accessibility requirements.

#### **Amendment 346**

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 *have* a quality management system in place that ensures compliance with this Regulation. *It* shall be documented in a systematic and orderly manner in the form of written policies, procedures *or* instructions, and *can be incorporated into an existing quality management system under Union sectoral legislative acts. It shall include at least the following aspects:* 

#### **Amendment 347**

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

#### **Amendment 348**

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## 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;

#### **Amendment 349**

## 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 or putting into *service of* high-risk AI systems;

#### **Amendment 350**

## 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 *relevant* competent authorities, including sectoral ones;

PE731.563v02-00 188/665 RR\1279290EN.docx

## Proposal for a regulation Article 17 – paragraph 2

Text proposed by the Commission

The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

#### Amendment

The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. Providers shall in any event respect the degree of rigour and the level of protection required to ensure compliance of their AI systems with this Regulation.

#### **Amendment 352**

Proposal for a regulation Article 18 – title

Text proposed by the Commission

Amendment

Obligation to draw up technical documentation

deleted

deleted

**Amendment 353** 

Proposal for a regulation Article 18 – paragraph 1

Text proposed by the Commission

Amendment

1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV.

**Amendment 354** 

Proposal for a regulation Article 18 – paragraph 2

Amendment

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.

deleted

deleted

#### **Amendment 355**

## Proposal for a regulation Article 19

Text proposed by the Commission

Amendment

#### Article 19

## Conformity assessment

- 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.
- 2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.

## Amendment 356

PE731.563v02-00 190/665 RR\1279290EN.docx

## 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 357**

## 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

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. Without prejudice to applicable Union or national law, the logs shall be kept for a period of at least 6 months. The retention period shall be in accordance with industry standards and appropriate to the intended purpose of high-risk AI system.

#### 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 take the necessary corrective actions to bring that system into conformity, to withdraw it, *to disable it* or to recall it, as appropriate.

In the cases referred to in the first paragraph, providers shall immediately inform:

- a. the distributors;
- b. the importers;
- c. the national competent authorities of the Member States in which they made the AI system available or put it into service;

and

d. where possible, the deployer.

**Amendment 358** 

Proposal for a regulation Article 21 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25, and the notified body if the high-risk AI system had to undergo a third-party conformity assessment in accordance with Article 43. Where applicable, they shall also investigate the causes in collaboration with the deployer.

**Amendment 359** 

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 the provider of the system *becomes aware of that risk*, that provider shall immediately inform the national *supervisory* 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 *relevant* corrective actions taken.

**Amendment 360** 

Proposal for a regulation Article 22 – paragraph 1 a (new)

PE731.563v02-00 192/665 RR\1279290EN.docx

#### Amendment

In the cases referred to inthe first paragraph, providers of the high-risk AI system shall immediately inform:

- a) the distributors;
- b) the importers;
- c) the national competent authorities of the Member States in which they made the AI system available or put it into service; and
- d) where possible, the deployers.

**Amendment 361** 

Proposal for a regulation Article 22 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25.

**Amendment 362** 

Proposal for a regulation Article 23 – title

Text proposed by the Commission

Amendment

Cooperation with competent authorities

Cooperation with competent authorities, *the Office and the Commission* 

**Amendment 363** 

Proposal for a regulation Article 23 – paragraph 1

Text proposed by the Commission

Amendment

Providers of high-risk AI systems shall, upon request by a national competent

Providers *and where applicable, deployers* of high-risk AI systems shall, upon *a* 

RR\1279290EN.docx 193/665 PE731.563v02-00

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.

reasoned 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.

#### **Amendment 364**

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, deployers 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.

#### Amendment 365

Proposal for a regulation Article 23 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

Any information obtained by a national competent authority or by the Commission pursuant to the provisions of this Article shall be considered a trade secret and be treated in compliance with the confidentiality obligations set out in

#### Article 70.

#### **Amendment 366**

## 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.

#### **Amendment 367**

Proposal for a regulation Article 25 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

1 a. The authorised representative shall reside or be established in one of the Member States where the activities pursuant to Article 2, paragraphs 1(cb) are taking place.

#### **Amendment 368**

Proposal for a regulation Article 25 – paragraph 1 b (new)

Text proposed by the Commission

### Amendment

1 b. The provider shall provide its authorised representative with the necessary powers and resources to comply with its tasks under this Regulation.

#### **Amendment 369**

## 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. It shall provide a copy of the mandate to the market surveillance authorities upon request, in one of the official languages of the institution of the Union determined by the national competent authority. For the purpose of this Regulation, the mandate shall empower the authorised representative to carry out the following tasks:

#### Amendment 370

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;

### **Amendment 371**

Proposal for a regulation Article 25 – paragraph 2 – point a a (new)

Text proposed by the Commission

### Amendment

(a a) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;

PE731.563v02-00 196/665 RR\1279290EN.docx

## 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, 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;

#### **Amendment 373**

## 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 *authority* takes to *reduce and mitigate the risks posed by* the highrisk AI system;

#### **Amendment 374**

Proposal for a regulation Article 25 – paragraph 2 – point c a (new)

Text proposed by the Commission

#### Amendment

(c a) where applicable, comply with the registration obligations referred in Article 51, or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of

RR\1279290EN.docx 197/665 PE731.563v02-00

#### Annex VIII is correct.

#### **Amendment 375**

Proposal for a regulation Article 25 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The authorised representative shall be mandated to be addressed, in addition to or instead of the provider, by, in particular, the national supervisory authority or the national competent authorities, on all issues related to ensuring compliance with this Regulation.

#### **Amendment 376**

Proposal for a regulation Article 25 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. 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 national supervisory 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.

#### **Amendment 377**

Proposal for a regulation Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

1. Before placing a high-risk AI system on the market, importers of such

Amendment

1. Before placing a high-risk AI system on the market, importers of such

PE731.563v02-00 198/665 RR\1279290EN.docx

system shall ensure that:

system shall ensure that such a system is in conformity with this Regulation by ensuring that:

#### **Amendment 378**

## 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

#### **Amendment 379**

## Proposal for a regulation Article 26 – paragraph 1 – point b

Text proposed by the Commission

(b) the provider has drawn up the technical documentation in accordance with Annex IV:

#### Amendment

(b) the provider has drawn up the technical documentation in accordance with *Article 11 and* Annex IV;

#### **Amendment 380**

Proposal for a regulation Article 26 – paragraph 1 – point c a (new)

Text proposed by the Commission

#### Amendment

(c a) where applicable, the provider has appointed an authorised representative in accordance with Article 25(1).

#### **Amendment 381**

Proposal for a regulation Article 26 – paragraph 2

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.

#### Amendment

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 counterfeit, 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.

#### Amendment 382

## Proposal for a regulation Article 26 – paragraph 3

Text proposed by the Commission

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.

#### Amendment

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 *and* on its packaging or its accompanying documentation, *where* applicable.

#### **Amendment 383**

## 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* 

## Amendment

5. Importers shall provide 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

PE731.563v02-00 200/665 RR\1279290EN.docx

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.

the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider *in* accordance with Article 20

#### **Amendment 384**

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 to reduce and mitigate the risks posed by the highrisk AI system.

#### **Amendment 385**

## Proposal for a regulation Article 27 – paragraph 1

Text proposed by the Commission

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.

#### 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 *their* obligations set out in this Regulation *in Articles 16 and 26 respectively*.

#### **Amendment 386**

Proposal for a regulation Article 27 – paragraph 2

RR\1279290EN.docx 201/665 PE731.563v02-00

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

Where a distributor considers or has 2 reason to consider, on the basis of the information in its possession that a highrisk 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, the relevant national competent authority, as applicable, to that effect.

#### **Amendment 387**

## 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

A distributor that considers or has 4. reason to consider, on the basis of the information in its possession, that a highrisk 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

PE731.563v02-00 202/665 RR\1279290EN.docx

## 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 *the* high-risk AI system shall provide that authority with all the information and documentation *in their possession or available to them, in accordance with the obligations of distributors as outlined in paragraph 1, that are* necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title.

#### **Amendment 389**

Proposal for a regulation Article 27 – paragraph 5 a (new)

Text proposed by the Commission

#### Amendment

5 a. Distributors shall cooperate with national competent authorities on any action those authorities take to reduce and mitigate the risks posed by the highrisk AI system.

## **Amendment 390**

Proposal for a regulation Article 28 – title

Text proposed by the Commission

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

Amendment

Responsibilities along the AI value chain of providers, distributors, importers, deployers or other third parties

## 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, *deployer* 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:

#### **Amendment 392**

Proposal for a regulation Article 28 – paragraph 1 – point a

Text proposed by the Commission

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

#### Amendment

(a) they put their name or trademarkt on a high-risk AI system already placed on the market or put into service;

## **Amendment 393**

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 make a substantial modification to a high-risk AI system that has already been placed on the market or has already been put into service and in a way that it remains a high-risk AI system in accordance with Article 6;

#### **Amendment 394**

Proposal for a regulation Article 28 – paragraph 1 – point b a (new)

PE731.563v02-00 204/665 RR\1279290EN.docx

#### Amendment

(b a) they make a substantial modification to an AI system, including a general purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such manner that the AI system becomes a high risk AI system in accordance with Article 6

#### **Amendment 395**

## Proposal for a regulation Article 28 – paragraph 2

Text proposed by the Commission

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.

#### Amendment

Where the circumstances referred to in paragraph 1, point (a) to (ba) occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered a provider of that specific AI system for the purposes of this Regulation. This former provider shall provide the new provider with the technical documentation and all other relevant and reasonably expected information capabilities of the AI system, technical access or other assistance based on the generally acknowledged state of the art that are required for the fulfilment of the obligations set out in this Regulation.

This paragraph shall also apply to providers of foundation models as defined in Article 3 when the foundation model is directly integrated in an high-risk AI system.

#### **Amendment 396**

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

2 a. The provider of a high risk AI system and the third party that supplies tools, services, components or processes that are used or integrated in the high risk AI system shall, by written agreement specify the information, capabilities, technical access, and or other assistance, based on the generally acknowledged state of the art, that the third party is required to provide in order to enable the provider of the high risk AI system to fully comply with the obligations under this Regulation.

The Commission shall develop and recommend non-binding model contractual terms between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used or integrated in high-risk AI systems in order to assist both parties in drafting and negotiating contracts with balanced contractual rights and obligations, consistent with each party's level of control. When developing non-binding model contractual terms, the Commission shall take into account possible contractual requirements applicable in specific sectors or business cases. The non-binding contractual terms shall be published and be available free of charge in an easily usable electronic format on the AI Office's website.

**Amendment 397** 

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

Text proposed by the Commission

Amendment

2 b. For the purposes of this Article, trade secrets shall be preserved and shall only be disclosed provided that all specific necessary measures pursuant to Directive

(EU) 2016/943 are taken in advance to preserve their confidentiality, in particular with respect to third parties. Where necessary, appropriate technical and organizational arrangements can be agreed to protect intellectual property rights or trade secrets.

Amendment 398

Proposal for a regulation Article 28 a (new)

Text proposed by the Commission

Amendment

#### Article 28 a

Unfair contractual terms unilaterally imposed on an SME or startup

- 1. A contractual term concerning the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations which has been unilaterally imposed by an enterprise on a SME or startup shall not be binding on the latter enterprise if it is unfair.
- 2. A contractual term is not to be considered unfair where it arises from applicable Union law.
- 3. A contractual term is unfair if it is of such a nature that it objectively impairs the ability of the party upon whom the term has been unilaterally imposed to protect its legitimate commercial interest in the information in question or its use grossly deviates from good commercial practice in the supply of tools, services, components or processes that are used or integrated in a high-risk AI system, contrary to good faith and fair dealing or creates a significant imbalance between the rights and the obligations of the parties in the contract. A contractual term is also unfair if it has the effect of shifting penalties referred to in Article 71 or

- associated litigation costs across parties to the contract, as referred to in Article 71(8).
- 4. A contractual term is unfair for the purposes of this Article if its object or effect is to:
- (a) exclude or limit the liability of the party that unilaterally imposed the term for intentional acts or gross negligence;
- (b) exclude the remedies available to the party upon whom the term has been unilaterally imposed in the case of non-performance of contractual obligations or the liability of the party that unilaterally imposed the term in the case of a breach of those obligations;
- (c) give the party that unilaterally imposed the term the exclusive right to determine whether the technical documentation, information supplied are in conformity with the contract or to interpret any term of the contract.
- 5. A contractual term shall be considered to be unilaterally imposed within the meaning of this Article if it has been supplied by one contracting party and the other contracting party has not been able to influence its content despite an attempt to negotiate it. The contracting party that supplied a contractual term shall bears the burden of proving that that term has not been unilaterally imposed.
- 6. Where the unfair contractual term is severable from the remaining terms of the contract, those remaining terms shall remain binding. The party that supplied the contested term shall not argue that the term is an unfair term.
- 7. This Article shall apply to all new contracts entered into force after ... [date of entry into force of this Regulation]. Businesses shall review existing contractual obligations that are subject to this Regulation by ...[three years after the date of entry into force of this

## Regulation].

8. Given the rapidity in which innovations occur in the markets, the list of unfair contractual terms within Article 28a shall be reviewed regularly by the Commission and be updated to new business practices if necessary.

#### **Amendment 399**

Proposal for a regulation Article 28 b (new)

Text proposed by the Commission

Amendment

#### Article 28 b

# Obligations of the provider of a foundation model

- 1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels.
- 2. For the purpose of paragraph 1, the provider of a foundation model shall:
- (a) demonstrate through appropriate design, testing and analysis that the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development
- (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to

- examine the suitability of the data sources and possible biases and appropriate mitigation
- (c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development;
- (d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;
- (e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);.
- (f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,
- (g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.

- When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;
- 3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities
- 4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition
- a) comply with the transparency obligations outlined in Article 52 (1),
- b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression,
- c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.

## 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 to ensure they* use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 *of this Article* 

#### **Amendment 401**

Proposal for a regulation Article 29 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

- 1 a. To the extent deployers exercise control over the high-risk AI system, they shall
- i) implement human oversight according to the requirements laid down in this Regulation
- (ii) ensure that the natural persons assigned to ensure human oversight of the high-risk AI systems are competent, properly qualified and trained, and have the necessary resources in order to ensure the effective supervision of the AI system in accordance with Article 14
- (iii) ensure that relevant and appropriate robustness and cybersecurity measures are regularly monitored for effectiveness and are regularly adjusted or updated.

**Amendment 402** 

Proposal for a regulation Article 29 – paragraph 2

PE731.563v02-00 212/665 RR\1279290EN.docx

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

#### **Amendment 403**

## 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 and 1a, to the extent the deployer exercises control over the input data, that deployer shall ensure that input data is relevant and sufficiently representative in view of the intended purpose of the high-risk AI system.

### **Amendment 404**

## 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

### Amendment

4. **Deployers** 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**. 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, **without undue delay**, inform the provider or distributor **and relevant national supervisory authorities** and suspend 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.

immediately inform first the provider, and then the importer or distributor and relevant national supervisory authorities when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. If the deployer is not able to reach the provider, Article 62 shall apply mutatis mutandis.

#### **Amendment 405**

## Proposal for a regulation Article 29 – paragraph 4 – subparagraph 1

Text proposed by the Commission

For *users* that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph 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.

#### Amendment

For *deployers* that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph 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.

## **Amendment 406**

## 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. **Deployers** of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent that such logs are under their control and are required for ensuring and demonstrating compliance with this Regulation, for ex-post audits of any reasonably foreseeable malfunction, incidents or misuses of the system, or for ensuring and monitoring for the proper functioning of the system throughout its

PE731.563v02-00 214/665 RR\1279290EN.docx

lifecycle. Without prejudice to applicable Union or national law, the logs shall be kept for a period of at least six months. The retention period shall be in accordance with industry standards and appropriate to the intended purpose of the high-risk AI system.

#### Amendment 407

## Proposal for a regulation Article 29 – paragraph 5 – subparagraph 1

Text proposed by the Commission

*Users* that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs as part of the documentation concerning internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

Amendment

**Deployers** that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs as part of the documentation concerning internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

#### Amendment 408

Proposal for a regulation Article 29 – paragraph 5 a (new)

Text proposed by the Commission

#### Amendment

5 a. Prior to putting into service or use a high-risk AI system at the workplace, deployers shall consult workers representatives with a view to reaching an agreement in accordance with Directive 2002/14/EC and inform the affected employees that they will be subject to the system.

**Amendment 409** 

Proposal for a regulation Article 29 – paragraph 5 b (new)

#### Amendment

5 b. Deployers of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies or undertakings referred to in Article 51(1a)(b) shall comply with the registration obligations referred to in Article 51.

#### **Amendment 410**

## 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. Where applicable, deployers 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, a summary of which shall be published, having regard to the specific use and the specific context in which the AI system is intended to operate. Deployers may revert in part to those data protection impact assessments for fulfilling some of the obligations set out in this article, insofar as the data protection impact assesment fulfill those obligations.

#### **Amendment 411**

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

Text proposed by the Commission

#### Amendment

6 a. Without prejudice to Article 52, deployers of high-risk AI systems referred to in Annex III, which make decisions or assist in making decisions related to natural persons, shall inform the natural

PE731.563v02-00 216/665 RR\1279290EN.docx

persons that they are subject to the use of the high-risk AI system. This information shall include the intended purpose and the type of decisions it makes. The deployer shall also inform the natural person about its right to an explanation referred to in Article 68c.

#### Amendment 412

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

Text proposed by the Commission

Amendment

6 b. Deployers shall cooperate with the relevant national competent authorities on any action those authorities take in relation with the high-risk system in order to implement this Regulation.

**Amendment 413** 

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

Prior to putting a high-risk AI system as defined in Article 6(2) into use, with the exception of AI systems intended to be used in area 2 of Annex III, deployers 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;

- (c) categories of natural persons and groups likely to be affected by the use of the system;
- (d) verification that the use of the system is compliant with relevant Union and national law on fundamental rights;
- (e) the reasonably foreseeable impact on fundamental rights of putting the high-risk AI system into use;
- (f) specific risks of harm likely to impact marginalised persons or vulnerable groups;
- (g) the reasonably foreseeable adverse impact of the use of the system on the environment;
- (h) a detailed plan as to how the harms and the negative impact on fundamental rights identified will be mitigated.
- (j) the governance system the deployer will put in place, including human oversight, complaint-handling and redress.
- 2. If a detailed plan to mitigate the risks outlined in the course of the assessment outlined in paragraph 1 cannot be identified, the deployer shall refrain from putting the high-risk AI system into use and inform the provider and the National supervisory authority without undue delay. National supervisory 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 the first use of the high-risk AI system. The deployer may, in similar cases, draw back on previously conducted fundamental rights impact assessment or existing assessment carried out by providers. If, during the use of the high-risk AI system, the deployer considers that the criteria listed in paragraph 1 are not longer met, it shall conduct a new fundamental rights impact

PE731.563v02-00 218/665 RR\1279290EN.docx

#### assessment.

4. In the course of the impact assessment, the deployer, with the exception of SMEs, shall shall notify national supervisory authority and relevant stakeholders and shall, to best extent possible, involve representatives of the persons or groups of persons that are likely 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 deployer shall allow a period of six weeks for bodies to respond. SMEs may voluntarily apply the provisions laid down in this paragraph.

In the case referred to in Article 47(1), public authorities may be exempted from this obligations.

- 5. The deployer that is a public authority or an undertaking referred to in Article 51(1a) (b) shall publish a summary of the results of the impact assessment as part of the registration of use pursuant to their obligation under 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 fundamental rights impact assessment referred to in paragraph 1 shall be conducted in conjunction with the data protection impact assessment. The data protection impact assessment shall be published as an addendum.

**Amendment 414** 

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. Those procedures shall be developed in cooperation between the notifying authorities of all Member States.

#### **Amendment 415**

# 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 the necessary expertise, such as a degree in an appropriate legal field, in the supervision of fundamental rights enshrined in the Charter of Fundamental Rights of the European Union.

## **Amendment 416**

# Proposal for a regulation Article 30 – paragraph 8

Text proposed by the Commission

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

## Amendment

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

PE731.563v02-00 220/665 RR\1279290EN.docx

complexity of the AI system in question.

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

#### Amendment 417

# 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 418**

# Proposal for a regulation Article 32 – paragraph 2

Text proposed by the Commission

2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

#### Amendment

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

#### Amendment

2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission of each conformity assessment body referred to in paragraph 1.

## **Amendment 419**

# 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

## Amendment

3. The notification *referred to in paragraph 2* shall include full details of the conformity assessment activities, the

RR\1279290EN.docx 221/665 PE731.563v02-00

module or modules and the artificial intelligence technologies concerned.

conformity assessment module or modules and the artificial intelligence technologies concerned, as well as the relevant attestation of competence.

#### **Amendment 420**

# 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 incudes documentary evidence referred to in Article 31(3.

## **Amendment 421**

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.

#### **Amendment 422**

PE731.563v02-00 222/665 RR\1279290EN.docx

# Proposal for a regulation Article 32 – paragraph 4 b (new)

Text proposed by the Commission

#### Amendment

4 b. Member States shall notify the Commission and the other Member States of conformity assessment bodies.

#### **Amendment 423**

# 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 organisational, quality management, resources and process requirements that are necessary to fulfil their tasks as well as the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (EU 2022/2555

## **Amendment 424**

## 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 425**

## Proposal for a regulation Article 33 – paragraph 4 a (new)

Text proposed by the Commission

#### Amendment

4 a. A conformity assessment pursuant to paragraph 1 shall be performed by employees of notified bodies who have not provided any other other service related to the matter assessed than the conformity assessment to the provider of a high-risk AI system nor to any legal person connected to that provider in the 12 months' period before the assessment and have committed to not providing them with such services in the 12 month period following the completion of the assessment.

#### **Amendment 426**

# 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

PE731.563v02-00 224/665 RR\1279290EN.docx

pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

#### Amendment 427

# Proposal for a regulation Article 34 – paragraph 3

Text proposed by the Commission

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

#### Amendment

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider. *Notified bodies shall make a list of their subsidiaries publicly available.* 

#### **Amendment 428**

# 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.

## Amendment 429

# Proposal for a regulation Article 35 – title

Text proposed by the Commission

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

#### Amendment

Identification numbers and lists of notified bodies

#### **Amendment 430**

RR\1279290EN.docx 225/665 PE731.563v02-00

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# Proposal for a regulation Article 36 – paragraph 1

Text proposed by the Commission

1. Where a notifying authority has suspicions or has been informed that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body investigation no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure. It shall also immediately inform the Commission and the other Member States accordingly.

### **Amendment 431**

# Proposal for a regulation Article 36 – paragraph 2

Text proposed by the Commission

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that notified body are either taken over by another notified body or kept available for the responsible notifying authorities at their request.

#### Amendment

Where a notifying authority has suspicions or has been informed that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure. It shall also immediately inform the Commission and the other Member States accordingly.

## Amendment

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that notified body are either taken over by another notified body or kept available for the responsible notifying authorities, and market surveillance authority at their request.

#### **Amendment 432**

## 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, where necessary, investigate all cases where there are reasons to doubt *the competence of* a notified body *or the continued fulfilment by a notified body of the applicable* requirements *and responsibilities*.

#### **Amendment 433**

# Proposal for a regulation Article 37 – paragraph 2

Text proposed by the Commission

2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification of the notified body concerned.

#### Amendment

2. The Notifying authority shall provide the Commission, on request, with all relevant information relating to the notification *or the maintenance of the competence* of the notified body concerned.

#### **Amendment 434**

# 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.

#### **Amendment 435**

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

Where the Commission ascertains 4 that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including suspension or withdrawal of the notification if necessary. Where the Member State fails to take the necessary corrective measures, the Commission may, by means of an implementing act, suspend, restrict or withdraw the designation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).

## **Amendment 436**

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.

### **Amendment 437**

Proposal for a regulation Article 40 – paragraph 1

Text proposed by the Commission

High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set

### Amendment

High-risk AI systems *and foundation models* 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 *in accordance with Regulation (EU)* 

PE731.563v02-00 228/665 RR\1279290EN.docx

out in Chapter 2 of this Title, to the extent those standards cover those requirements.

1025/2012 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title or Article 28b, to the extent those standards cover those requirements.

#### **Amendment 438**

Proposal for a regulation Article 40 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall issue standardisation requests covering all requirements of this Regulation, in accordance with Article 10 of Regulation EU (No)1025/2012 by... [two months after the date of entry into force of this Regulation]. When preparing standardisation request, the Commission shall consult the AI Office and the Advisory Forum;

## **Amendment 439**

Proposal for a regulation Article 40 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be consistent, including with the sectorial law listed in Annex II, and aimed at ensuring that AI systems or foundation models placed on the market or put into service in the Union meet the relevant requirements laid down in this Regulation;

#### **Amendment 440**

# Proposal for a regulation Article 40 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

The actors involved in the standardisation process shall take into account the general principles for trustworthy AI set out in Article 4(a), seek to promote investment and innovation in AI as well as competitiveness and growth of the Union market, and contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and ensure a balanced representation of interests and effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012

**Amendment 441** 

Proposal for a regulation Article 41 – paragraph 1

Text proposed by the Commission

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).

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#### Amendment 442

## Proposal for a regulation Article 41 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

- 1 a. The Commission may, by means of implementing act adopted in accordance with the examination procedure referred to in Article 74(2) and after consulting the AI Office and the AI Advisory Forum, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title or Article 28b wherein all of the following conditions are fulfilled:
- (a) there is no reference to harmonised standards already published in the Official Journal of the European Union related to the essential requirement(s), unless the harmonised standard in question is an existing standard that must be revised;
- (b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential requirement(s) set out in Chapter 2;
- (c) the request referred to in point (b) has not been accepted by any of the European standardisation organisations; or there are undue delays in the establishment of an appropriate harmonised standard; or the standard provided does not satisfy the requirements of the relevant Union law, or does not comply with the request of the Commission.

#### **Amendment 443**

Proposal for a regulation Article 41 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1 b. Where the Commission considers

there to be a need to address specific fundamental rights concerns, common specifications adopted by the Commission in accordance with paragraph 1a shall also address those specific fundamental rights concerns.

### **Amendment 444**

Proposal for a regulation Article 41 – paragraph 1 c (new)

Text proposed by the Commission

#### Amendment

1 c. The Commission shall develop common specifications for the methodology to fulfil the reporting and documentation requirement on the consumption of energy and resources during development, training and deployment of the high risk AI system.

#### **Amendment 445**

# 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, throughout the whole process of drafting the common specifications referred to in paragraphs 1a and 1b, regularly consult the AI Office and the Advisory Forum, the European standardisation organisations and bodies or expert groups established under relevant sectorial Union law as well as other relevant stakeholders. The Commission shall fulfil the objectives referred to in Article 40 (1c) and duly justify why it decided to resort to common specifications.

Where the Commission intends to adopt common specifications pursuant to paragraph 1a of this Article, it shall also clearly identify the specific fundamental

PE731.563v02-00 232/665 RR\1279290EN.docx

## rights concern to be addressed.

When adopting common specifications pursuant to paragraphs 1a and 1b of this Article, the Commission shall take into account the opinion issued by the AI Office referred to in Article 56e(b) of this Regulation. Where the Commission decides not to follow the opinion of the AI Office, it shall provide a reasoned explanation to the AI Office.

#### **Amendment 446**

# Proposal for a regulation Article 41 – paragraph 3

Text proposed by the Commission

3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph *I* 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.

### **Amendment 447**

Proposal for a regulation Article 41 – paragraph 3 a (new)

Text proposed by the Commission

### Amendment

3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph *1a and 1b* 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

### Amendment

3 a. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal acts referred to in paragraph 1 and 1b, or parts thereof

# which cover the same requirements set out in Chapter 2 of this Title.

#### **Amendment 448**

## 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 *meet the requirements referred to in Chapter II to a level* at least equivalent thereto;

#### **Amendment 449**

# 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 *contextual* 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).

### **Amendment 450**

# 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-

## Amendment

1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-

PE731.563v02-00 234/665 RR\1279290EN.docx

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:

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;

#### Amendment 451

# 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

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

#### **Amendment 452**

# 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 of the technical documentation, with the involvement of a notified body, referred to in Annex VII;

## Amendment 453

## 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

#### Amendment

In demonstrating the compliance of a highrisk AI system with the requirements set out in Chapter 2 of this Title, the provider shall follow the conformity assessment procedure set out in Annex VII in the

RR\1279290EN.docx 235/665 PE731.563v02-00

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.

## following cases:

- (a) where harmonised standards referred to in Article 40, 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 and common specifications referred to in Article 41 are not available;
- (b) where the technical specifications referred to in point (a) exist but the provider has not applied them or has applied them only in part;
- (c) where one or more of the technical specifications referred to in point (a) has been published with a restriction and only on the part of the standard that was restricted;
- (d) when the provider considers that the nature, design, construction or purpose of the AI system necessitate third party verification, regardless of its risk level.

#### **Amendment 454**

# 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.

#### **Amendment 455**

## Proposal for a regulation Article 43 – paragraph 4 – introductory part

Text proposed by the Commission

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

#### Amendment

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

#### Amendment 456

Proposal for a regulation Article 43 – paragraph 4 a (new)

Text proposed by the Commission

## Amendment

4 a. The specific interests and needs of SMEs 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 share;

#### Amendment 457

# 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

#### 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.

necessary in light of technical progress. When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected;

#### **Amendment 458**

# 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. 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. When preparing such delegated acts, the Commission shall consult the AI Office and the stakeholders affected;

#### **Amendment 459**

# Proposal for a regulation Article 44 – paragraph 1

Text proposed by the Commission

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

#### Amendment

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

PE731.563v02-00 238/665 RR\1279290EN.docx

## the notified body;

#### Amendment 460

## Proposal for a regulation Article 44 – paragraph 2

Text proposed by the Commission

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

## Amendment 461

# 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 462**

Proposal for a regulation Article 45 – paragraph 1

#### Amendment

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

## 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.

## Text proposed by the Commission

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

#### Amendment

Member States shall ensure that an appeal procedure against decisions of the notified bodies, *including on issued conformity certificates* is available to parties having a legitimate interest in that decision.

#### **Amendment 463**

# Proposal for a regulation Article 46 – paragraph 3

Text proposed by the Commission

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

#### Amendment

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

#### **Amendment 464**

# Proposal for a regulation Article 47 – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 43, any *market surveillance* authority may authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of *public security or* the protection of life and health of persons, environmental protection and the protection of *key industrial and infrastructural assets*. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those

#### Amendment

1. By way of derogation from Article 43, any *national supervisory* authority may *request a judicial authority to* authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of the protection of life and health of persons, environmental protection and the protection of *critical infrastructure*. 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

PE731.563v02-00 240/665 RR\1279290EN.docx

procedures shall be undertaken without undue delay.

completion of those procedures shall be undertaken without undue delay;

#### **Amendment 465**

# 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 *national supervisory* authority *and judicial authority conclude* that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The *national supervisory* authority shall inform the Commission, *the AI office*, and the other Member States of any *request made and any subsequent* authorisation issued pursuant to paragraph 1;

### **Amendment 466**

# 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 national supervisory authority for an authorisation issued by a national supervisory authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified;

## **Amendment 467**

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 468

# 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 469

# 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

#### Amendment

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 national supervisory 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 and the AI *Office*; 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);

#### Amendment

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

### Amendment

1. The provider shall draw up a written *machine readable, physical or* 

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.

electronic 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 for 10 years after the AI high-risk system has been placed on the market or put into service. A copy of the EU declaration of conformity shall be submitted to the national supervisory authority and the relevant national competent authorities upon request;

#### Amendment 470

# Proposal for a regulation Article 48 – paragraph 2

Text proposed by the Commission

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

## Amendment

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

#### **Amendment 471**

# Proposal for a regulation Article 48 – paragraph 3

Text proposed by the Commission

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

## Amendment

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

harmonisation legislation to which the declaration relates.

harmonisation legislation to which the declaration relates.

#### Amendment 472

# 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 AI Office, 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 473**

# 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 *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 of use;

# **Amendment 474**

Proposal for a regulation Article 49 – paragraph 1 a (new)

PE731.563v02-00 244/665 RR\1279290EN.docx

## Text proposed by the Commission

#### Amendment

1 a. For digital only high-risk AI systems, a digital CE marking shall be used, only if it can be easily accessed via the interface from which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.

#### **Amendment 475**

# Proposal for a regulation Article 49 – paragraph 3

Text proposed by the Commission

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

#### Amendment

3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the provider's authorised representative. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking;

## **Amendment 476**

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 law 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 law.

#### Amendment 477

## 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 10 years, after the AI system has been placed on the market or put into service keep at the disposal of the national *supervisory authority and the national* competent authorities:

#### **Amendment 478**

# 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 or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60, in accordance with Article 60(2);

#### **Amendment 479**

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 following categories of deployers shall register the use of that AI system in the EU database referred to in Article 60:

a) deployers who are public authorities or Union institutions, bodies, offices or agencies or deployers acting on their behalf;

PE731.563v02-00 246/665 RR\1279290EN.docx

b) deployers who are undertakings designated as a gatekeeper under Regulation (EU) 2022/1925.

**Amendment 480** 

Proposal for a regulation Article 51 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

Deployers who do not fall under subparagraph 1a. shall be entitled to voluntarily register the use of a high-risk AI system referred to in Article 6(2) in the EU database referred to in Article 60.

**Amendment 481** 

Proposal for a regulation Article 51 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

An updated registration entry must be completed immediately following each substantial modification.

**Amendment 482** 

Proposal for a regulation Title IV

Text proposed by the Commission

Amendment

TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS

TRANSPARENCY OBLIGATIONS

**Amendment 483** 

Proposal for a regulation Article 52 – title

RR\1279290EN.docx 247/665 PE731.563v02-00

Text proposed by the Commission

Amendment

Transparency obligations *for certain AI* systems

Transparency obligations

#### **Amendment 484**

## 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 the AI system, the provider itself or the user informs the natural person exposed to an AI system that they are interacting with an AI system in a timely, clear and intelligible manner, unless this is obvious from the circumstances and the context of use.

Where appropriate and 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, as well as the existing rights and processes that, according to Union and national law, allow natural persons or their representatives to object against the application of such systems to them and to seek judicial redress against decisions taken by or harm caused by AI systems, including their right to seek an explanation. 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.

PE731.563v02-00 248/665 RR\1279290EN.docx

#### **Amendment 485**

# 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

Users of an emotion recognition 2. system or a biometric categorisation system which is not prohibited pursuant to Article 5 shall inform in a timely, clear and intelligible manner of the operation of the system the natural persons exposed thereto and obtain their consent prior to the processing of their biometric and other personal data in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable. 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 486**

# Proposal for a regulation Article 52 – paragraph 3 – subparagraph 1

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

Users of an AI system that 3. generates or manipulates text, 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 in an appropriate, timely, clear and visible manner that the content has been artificially generated or manipulated, as well as, whenever possible, the name of the natural or legal person that generated or manipulated it. 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.

Amendment 487

Proposal for a regulation Article 52 – paragraph 3 – subparagraph 2

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

3a. **Paragraph 3** shall not apply where the use of an AI system that generates or manipulates text, audio or visual content is authorized by law or *if* 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. Where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video games visuals and analogous work or programme, transparency obligations set out in paragraph 3 are limited to disclosing of the existence of such generated or manipulated content in an appropriate clear and visible manner that does not hamper the display of the work and disclosing the applicable copyrights, where relevant. It shall also not prevent law enforcement authorities from using AI systems intended to detect deep fakes and prevent, investigate and prosecute criminal offences linked with their use

**Amendment 488** 

Proposal for a regulation Article 52 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The information referred to in

PE731.563v02-00 250/665 RR\1279290EN.docx

paragraphs 1 to 3 shall be provided to the natural persons at the latest at the time of the first interaction or exposure. It shall be accessible to vulnerable persons, such as persons with disabilities or children, complete, where relevant and appropriate, with intervention or flagging procedures for the exposed natural person taking into account the generally acknowledged state of the art and relevant harmonised standards and common specifications.

#### **Amendment 489**

# 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 490**

Proposal for a regulation Article 53 – paragraph 1 a (new)

Text proposed by the Commission

### Amendment

1. Member States shall establish at least one AI regulatory sandbox at national level, which shall be operational at the latest on the day of the entry into application of this Regulation This sandbox can also be established jointly with one or several other Member States;

#### Amendment

1 a. Additional AI regulatory sandboxes at regional or local levels or jointly with other Member States may also

### be established;

#### **Amendment 491**

Proposal for a regulation Article 53 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1 b. The Commission and the European Data Protection Supervisor, on their own, jointly or in collaboration with one or more Member States may also establish AI regulatory sandboxes at Union level;

#### **Amendment 492**

Proposal for a regulation Article 53 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1 c. Establishing authorities shall allocate sufficient resources to comply with this Article effectively and in a timely manner;

#### **Amendment 493**

Proposal for a regulation Article 53 – paragraph 1 d (new)

Text proposed by the Commission

Amendment

1 d. AI regulatory sandboxes shall, in accordance with criteria set out in Article 53a, provide for a controlled environment that fosters innovation and 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 agreed between the prospective providers and the establishing authority;

PE731.563v02-00 252/665 RR\1279290EN.docx

Proposal for a regulation Article 53 – paragraph 1 e (new)

Text proposed by the Commission

## Amendment

- 1 e. The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:
- a) for the competent authorities to provide guidance to AI systems prospective providers providers to achieve regulatory compliance with this Regulation or where relevant other applicable Union and Member States legislation;
- b) for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems;
- c) regulatory learning in a controlled environment.

## **Amendment 495**

Proposal for a regulation Article 53 – paragraph 1 f (new)

Text proposed by the Commission

## Amendment

1 f. Establishing authorities shall provide guidance and supervision within the sandbox with a view to identify risks, in particular to fundamental rights, democracy and rule of law, health and safety and the environment, test and demonstrate mitigation measures for identified risks, and their effectiveness and ensure compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation;

# Proposal for a regulation Article 53 – paragraph 1 f (new)

Text proposed by the Commission

## Amendment

1 g. Establishing authorities shall provide sandbox prospective providers who develop high-risk AI systems with guidance and supervision on how to fulfil the requirements set out in this Regulation, so that the AI systems may exit the sandbox being in presumption of conformity with the specific requirements of this Regulation that were assessed within the sandbox. Insofar as the AI system complies with the requirements when exiting the sandbox, it shall be presumed to be in conformity with this regulation. In this regard, the exit reports created by the establishing authority shall be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks:

## Amendment 497

# 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. **Establishing authorities** 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, **or in cases referred to in paragraph 1b the EDPS**, and those other national authorities are associated to the operation of the AI regulatory sandbox **and involved in the supervision of those aspects to the full** 

PE731.563v02-00 254/665 RR\1279290EN.docx

extent of their respective tasks and powers;

## **Amendment 498**

# 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, including at regional or local level. Any significant risks to fundamental rights, democracy and rule of law, health and safety or the environment identified during the development and testing of such AIsystems shall result in immediate and adequate mitigation. Competent authorities shall have the power to temporarily or permanently suspend the testing process, or participation in the sandbox if no effective mitigation is possible and inform the AI office of such decision;

## **Amendment 499**

# 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. **Prospective providers** 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. However, provided that the prospective provider(s) respect the specific plan referred to in paragraph 1c and the terms and conditions for their participation and follow in good faith the guidance given by the establishing

authorities, no administrative fines shall be imposed by the authorities for infringements of this Regulation;

## Amendment 500

# 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 501

Proposal for a regulation Article 53 – paragraph 5 a (new)

Text proposed by the Commission

## Amendment

5. **Establishing** authorities shall coordinate their activities and cooperate within the framework of the **AI office**;

## Amendment

5 a. Establishing authorities shall inform the AI Office of the establishment of a sandbox and may ask for support and guidance. A list of planned and existing sandboxes shall be made publicly available by the AI office and kept up to date in order to encourage more interaction in the regulatory sandboxes and transnational cooperation;

**Amendment 502** 

PE731.563v02-00 256/665 RR\1279290EN.docx

# Proposal for a regulation Article 53 – paragraph 5 b (new)

Text proposed by the Commission

#### Amendment

5 b. Establishing authorities shall submit to the AI office and, unless the Commission is the sole establishing authority, to the Commission, annual reports, starting one year after the establishment of the sandbox and then every year until its termination and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup and, where relevant, on the application and possible revision of this Regulation and other Union law supervised within the sandbox. Those annual reports or abstracts thereof shall be made available to the public, online;

## **Amendment 503**

# 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 Commission shall develop a single and dedicated interface containing all relevant information related to sandboxes, together with a single contact point at Union level to interact with the regulatory sandboxes and to allow stakeholders to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity of innovative products, services, business models embedding AI technologies;

The Commission shall proactively coordinate with national, regional and also local authorities, where relevant;

Proposal for a regulation Article 53 – paragraph 6 a (new)

Article 53 – paragraph 6a (new)

Text proposed by the Commission

Amendment

6 a. For the purpose of paragraph 1 and 1a, the Commission shall play a complementary role, enabling Member States 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;

## Amendment 505

Proposal for a regulation Article 53 a (new) Article 53a (new) – Title

Text proposed by the Commission

Amendment

## Article 53 a

Modalities and functioning of AI regulatory sandboxes

- 1. In order to avoid fragmentation across the Union, the Commission, in consultation with the AI office, shall adopt a delegated act detailing the modalities for the establishment, development, implementation, functioning and supervision 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 based on the provisions set out in this Article;
- 2. The Commission is empowered to adopt delegated acts in accordance with the procedure referred to in Article 73, no later than 12 months following the entry

PE731.563v02-00 258/665 RR\1279290EN.docx

into force of this Regulation and shall ensure that:

- a) regulatory sandboxes are open to any applying prospective provider of an AI system who fulfils eligibility and selection criteria. The criteria for accessing to the regulatory sandbox are transparent and fair and establishing authorities inform applicants of their decision within 3 months of the application;
- b) regulatory sandboxes allow broad and equal access and keep up with demand for participation;
- c) access to the AI regulatory sandboxes is free of charge for SMEs and start-ups without prejudice to exceptional costs that establishing authorities may recover in a fair and proportionate manner;
- d) regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations (SMEs, start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and digital innovation hubs, centers of excellence, individual researchers), in order to allow and facilitate cooperation with the public and private sector;
- e) they allow prospective providers to to fulfil, in a controlled environment, the conformity assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69;
- f) procedures, processes and administrative requirements for application, selection, participation and exiting the sandbox are simple, easily intelligible, clearly communicated in order to facilitate the participation of SMEs and start-ups with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in a regulatory sandbox

established by a Member State, by the Commission, or by the EDPS is mutually and uniformly recognised and carries the same legal effects across the Union;

- g) participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project.
- h) the sandboxes shall facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity as well as minimisation of risks to fundamental rights, environment and the society at large
- 3. Prospective providers in the sandboxes, in particular SMEs and start-ups, shall be facilitated access to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and certification and consultation, and to other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities;

**Amendment 506** 

Proposal for a regulation Article 54 – title

Text proposed by the Commission

Further processing of *personal* data for developing certain AI systems in the public interest in the AI regulatory sandbox

Amendment

Further processing of data for developing certain AI systems in the public interest in the AI regulatory sandbox

**Amendment 507** 

# Proposal for a regulation Article 54 – paragraph 1 – introductory part

Text proposed by the Commission

In the AI regulatory sandbox 1. 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 solely for the purposes of developing and testing certain AI systems in the sandbox when all of the following conditions are met:

## **Amendment 508**

Proposal for a regulation Article 54 – paragraph 1 – point a – introductory part

Text proposed by the Commission

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

- Amendment
- AI systems shall be developed for (a) safeguarding substantial public interest in one or more of the following areas:
- (ii) public safety and public health, including disease detection, diagnosis prevention, control and treatment;
- (iii) a high level of protection and improvement of the quality of the environment, protection of biodiversity, pollution as well as climate change mitigation and adaptation;
- (iii a) safety and resilience of transport systems, critical infrastructure and networks.

## Amendment 509

Proposal for a regulation Article 54 – paragraph 1 – point a – point i

Text proposed by the Commission

Amendment

*(i)* the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal deleted

RR\1279290EN.docx 261/665 PE731.563v02-00 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 510**

# 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 Article 35 of Regulation (EU) 2016/679 and in Article 35 of Regulation (EU) 2018/1725 may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;

## **Amendment 511**

# 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 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 *prospective provider* and only authorised persons have access to that *those* data;

## **Amendment 512**

Proposal for a regulation Article 54 – paragraph 1 – point f

PE731.563v02-00 262/665 RR\1279290EN.docx

# (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 do not lead to measures or decisions affecting the data subjects nor affect the application of their rights laid down in Union law on the protection of personal data;

## **Amendment 513**

# 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 514

# 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;

## **Amendment 515**

# 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, *hypotheses*, and expected results, published on the website of the competent authorities;

## **Amendment 516**

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 socioeconomic 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

PE731.563v02-00 264/665 RR\1279290EN.docx

# 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.

Member States shall support civil society and social stakeholders to lead or participate in such projects;

## Amendment 517

Proposal for a regulation Article 55 – title

Text proposed by the Commission

Amendment

Measures for *small-scale providers* and users

Measures for *SMEs*, *start-ups* and users

## **Amendment 518**

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, *established in the Union*, with priority access to the AI regulatory sandboxes, to the extent that they fulfil the eligibility conditions;

## **Amendment 519**

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

Amendment

(b) organise specific awareness raising and enhanced digital skills development

Regulation tailored to the needs of *the small-scale providers* and users;

activities *on* the application of this Regulation tailored to the needs of *SMEs*, *start-ups* and users;

#### Amendment 520

# 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) utilise existing dedicated channels and where appropriate, establish new dedicated channels for communication with SMEs, start-ups, users and other innovators to provide guidance and respond to queries about the implementation of this Regulation;

## **Amendment 521**

Proposal for a regulation Article 55 – paragraph 1 – point c a (new)

Text proposed by the Commission

## Amendment

(ca) foster the participation of SMEs and other relevant stakeholders in the standardisation development process.

## **Amendment 522**

# 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*, *start-ups and users* shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to *development stage*, their *size*, *market* size and market *demand*. The Commission shall regularly assess the certification and

PE731.563v02-00 266/665 RR\1279290EN.docx

compliance costs for SMEs and start-ups, including through transparent consultations with SMEs, start-ups and users and shall work with Member States to lower such costs where possible. The Commission shall report on these findings to the European Parliament and to the Council as part of the report on the evaluation and review of this Regulation provided for in Article 84(2).

**Amendment 523** 

Proposal for a regulation **Article 56 – SECTION 1 – Title** 

Text proposed by the Commission

Amendment

Title

SECTION 1: General provisions on the European Artificial Intelligence Office

**Amendment 524** 

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* 

Amendment 525

Proposal for a regulation Article 56 – paragraph 1

Text proposed by the Commission

A 'European Artificial Intelligence Board' (the 'Board') is established.

Amendment

The 'European Artificial Intelligence Office' (the 'AI Office') is hereby established. The AI Office shall be an independent body of the Union. It shall have legal personality.

# Proposal for a regulation Article 56 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

- 2. The **Board** shall **provide** advice and assistance to the Commission in order to:
- 2. The AI Office shall have a secretariat, and shall be adequately funded and staffed for the purpose of performing its tasks pursuant to this Regulation.

**Amendment 527** 

Proposal for a regulation Article 56 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The seat of the AI Office shall be in Brussels.

**Amendment 528** 

Proposal for a regulation Article 56 a (new)

Text proposed by the Commission

Amendment

Article 56 a

Structure

The administrative and management structure of the AI Office shall comprise:

- (a) a management board, including a chair
- (b) a secretariat managed by an executive director;
- (c) an advisory forum.

Amendment 529

PE731.563v02-00 268/665 RR\1279290EN.docx

# Proposal for a regulation Article 56 b (new)

Text proposed by the Commission

Amendment

Article 56 b

Tasks of the AI Office

The AI Office shall carry out the following tasks:

- a) support, advise, and cooperate with Member States, national supervisory authorities, the Commission and other Union institutions, bodies, offices and agencies with regard to the implementation of this Regulation;
- b) monitor and ensure the effective and consistent application of this Regulation, without prejudice to the tasks of national supervisory authorities;
- c) contribute to the coordination among national supervisory authorities responsible for the application of this Regulation,
- d) serve as a mediator in discussions about serious disagreements that may arise between competent authorities regarding the application of the Regulation
- e) coordinate joint investigations, pursuant to Article 66a;
- f) contribute to the effective cooperation with the competent authorities of third countries and with international organisations,
- g) collect and share Member States' expertise and best practices and to assist Member States national supervisory authorities and the Commission in developing the organizational and technical expertise required for the implementation of this Regulation, including by means of facilitating the creation and maintenance of a Union

## pool of experts

- h) examine, on its own initiative or upon the request of its management board or the Commission, questions relating to the implementation of this Regulation and to issue opinions, recommendations or written contributions including with regard to:
- (i) technical specifications or existing standards; (ii) the Commission's guidelines
- (iii) codes of conduct and the application thereof, in close cooperation with industry and other relevant stakeholders;
- (iv) the possible revision of the Regulation, the preparation of the delegated acts, and possible alignments of this Regulation with the legal acts listed in Annex II;
- (v) trends, such as European global competitiveness in artificial intelligence, the uptake of artificial intelligence in the Union, the development of digital skills, and emerging systemic threats relating to artificial intelligence
- (vi) guidance on how this Regulation applies to the ever evolving typology of AI value chains, in particular on the resulting implications in terms of accountability of all the entities involved

## i) issue:

- (i) an annual report that includes an evaluation of the implementation of this Regulation, a review of serious incident reports as referred to in Article 62 and the functioning of the database referred to in Article 60 and
- (ii) recommendations to the Commission on the categorisation of prohibited practices, high-risk AI systems referred to in Annex III, the codes of conduct referred to in Article 69, and the application of the general principles outlines in Article 4a

PE731.563v02-00 270/665 RR\1279290EN.docx

- j) assist authorities in the establishment and development of regulatory sandboxes and to facilitate cooperation among regulatory sandboxes;
- k) organise meetings with Union agencies and governance bodies whose tasks are related to artificial intelligence and the implementation of this Regulation;
- l)organise quarterly consultations with the advisory forum, and, where appropriate, public consultations with other stakeholders, and to make the results of those consultations public on its website;
- m) promote public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems;
- n) facilitate the development of common criteria and a shared understanding among market operators and competent authorities of the relevant concepts provided for in this Regulation;
- o) provide monitoring of foundation models and to organise a regular dialogue with the developers of foundation models with regard to their compliance as well as AI systems that make use of such AI models
- p) provide interpretive guidance on how the AI Act applies to the ever evolving typology of AI value chains, and what the resulting implications in terms of accountability of all the entities involved will be under the different scenarios based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards;
- q) provide particular oversight and monitoring and institutionalize regular dialogue with the providers of foundation models about the compliance of foundation models as well as AI systems that make use of such AI models with Article 28b of this Regulation, and about industry best practices for self-

governance. Any such meeting shall be open to national supervisory authorities, notified bodies and market surveillance authorities to attend and contribute

r) issue and periodically update guidelines on the thresholds that qualify training a foundation model as a large training run, record and monitor known instances of large training runs, and issue an annual report on the state of play in the development, proliferation, and use of foundation models alongside policy options to address risks and opportunities specific to foundation models.

s) promote AI literacy pursuant to Article 4b.

## Amendment 530

Proposal for a regulation Article 56 c (new)

Text proposed by the Commission

Amendment

Article 56 c

Accountability, independence, and transparency

1. The AI Office shall:

a. be accountable to the European Parliament and to the Council in accordance with this Regulation;

b. act independently when carrying out its tasks or exercising its powers; and

c. ensure a high level of transparency concerning its activities and develop good administrative practices in that regard.

Regulation (EC) No 1049/2001 shall apply to documents held by the AI Office.

## **Amendment 531**

Proposal for a regulation Article - 57 a (new) – SECTION 2 – title

PE731.563v02-00 272/665 RR\1279290EN.docx

## Title

# SECTION 2: Management Board

#### Amendment 532

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 the following members:
- (a) one representative of each Member State's national supervisory authority;
- (b) one representative from the Commission;
- (c) one representative from the European Data Protection Supervisor (EDPS);
- (d) one representative from the European Union Agency for Cybersecurity (ENISA);
- (e) one representative from the Fundamental Rights Agency (FRA)

Each representative of a national supervisory authority shall have one vote. The representatives of the Commission, the EDPS, the ENISA and the FRA shall not have voting rights. Each member shall have a substitute. The appointment of members and substitute members of the management board shall take into account the need to gender balance. The members of the management board and their substitute members shall be made public.

2. The members and substitutes members of the management board shall not hold conflicting positions or commercial

interests with regard to any topic related to the application of this Regulation.

3. The rules for the meetings and voting of the management board and the appointment and removal of the Executive Director shall be laid down in the rules of procedure referred to in Article – 57 b, point (a).

## **Amendment 533**

Proposal for a regulation Article - 57 b (new)

Text proposed by the Commission

Amendment

## Article - 57 b

Functions of the management board

- 1. The management board shall have the following tasks:
- (a) to make strategic decisions on the activities of the AI Office and to adopt its rules of procedure by a two-thirds majority of its members;
- (b) to implement its rules of procedure;
- (c) to adopt the AI Office's single programming document as well as it annual public report and transmit both to the European Parliament, to the Council, to the Commission, and to the Court of Auditors;
- (d) to adopt the AI Office's budget;
- (e) to appoint the executive director and, where relevant, to extend or curtail the executive director's term of office or remove him or her from office;
- (f) to decide on the establishment of the AI Office's internal structures and, where necessary, the modification of those internal structures necessary for the fulfilment of the AI Office tasks;

PE731.563v02-00 274/665 RR\1279290EN.docx

# 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 two deputy Chairs from among its voting members, by simple majority.
- 2. The term of office of the Chair and of the deputy Chairs shall be four years. The terms of the Chair and of the deputy Chairs renewable once.

**Amendment 535** 

Proposal for a regulation Article 57 – SECTION 3 – title

Text proposed by the Commission

Amendment

Structure of the Board

Secretariat

**Amendment 536** 

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 activities of the secretariat shall be managed by an executive director. The executive director shall be accountable to the management board. Without prejudice to the respective powers of the management board and the Union institutions, the executive director shall neither seek nor take instructions from any government or from any other body

**Amendment 537** 

RR\1279290EN.docx 275/665 PE731.563v02-00

# 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 executive director shall attend hearings on any matter linked to the AI Office's activities and shall report on the performance of the executive director's duties when invited to do so by the European Parliament or the Council.

## **Amendment 538**

# 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 executive director shall represent the AI Office, including in international fora for cooperation with regard to artificial intelligence;

## Amendment 539

# 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

#### Amendment

4. The secretariat shall provide the management board and the advisory forum with the analytical, administrative and logistical support necessary to fulfil the tasks of the AI Office, including by:

PE731.563v02-00 276/665 RR\1279290EN.docx

end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

- (a) Implementing the decisions, programmes and activities adopted by the management board;
- (b) preparing each year the draft single programming document, the draft budget, the annual activity report on the AI Office, the draft opinions and the draft positions of the AI Office, and submit them to the management board
- (c) Coordinating with international fora for cooperation on artificial intelligence;

**Amendment 540** 

Proposal for a regulation Article 58 – SECTION 4 – title

Text proposed by the Commission

Amendment

Tasks of the Board

Advisory Forum

**Amendment 541** 

Proposal for a regulation Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

The advisory forum shall provide the AI Office with stakeholder input in matters relating to this Regulation, in particular with regard to the tasks set out in Article 56b point (l).

**Amendment 542** 

Proposal for a regulation Article 58 – paragraph 2 (new)

## Amendment

The membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, startups, SMEs, civil society, the social partners and academia. The membership of the advisory forum shall be balanced with regard to commercial and noncommercial interests and, within the category of commercial interests, with regards to SMEs and other undertakings.

## **Amendment 543**

Proposal for a regulation Article 58 – paragraph 3 (new)

Text proposed by the Commission

Amendment

The management board shall appoint the members of the advisory forum in accordance with the selection procedure established in the AI Office's rules of procedure and taking into account the need for transparency and in accordance with the criteria set out in paragraph 2;

## **Amendment 544**

Proposal for a regulation Article 58 – paragraph 4 (new)

Text proposed by the Commission

Amendment

The term of office of the members of the advisory forum shall be two years, which may be extended by up to no more than four years.

## **Amendment 545**

Proposal for a regulation Article 58 – paragraph 5 (new)

PE731.563v02-00 278/665 RR\1279290EN.docx

Amendment

The European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the Advisory Forum. The Joint Research Centre shall be permanent member, without voting rights.

**Amendment 546** 

Proposal for a regulation Article 58 – paragraph 6 (new)

Text proposed by the Commission

Amendment

The advisory forum shall draw up its rules of procedure. It shall elect two co-Chairs from among its members, in accordance with criteria set out in paragraph 2. The term of office of the co-Chairs shall be two years, renewable once.

**Amendment 547** 

Proposal for a regulation Article 58 – paragraph 7 (new)

Text proposed by the Commission

Amendment

The advisory forum shall hold meetings at least four times a year. The advisory forum may invite experts and other stakeholders to its meetings. The executive director may attend, ex officio, the meetings of the advisory forum.

**Amendment 548** 

Proposal for a regulation Article 58 – paragraph 8 (new)

Amendment

In fulfilling its role as set out in paragraph 1, the advisory forum may prepare opinions, recommendations and written contributions.

**Amendment 549** 

Proposal for a regulation Article 58 – paragraph 9 (new)

Text proposed by the Commission

Amendment

The advisory forum may establish standing or temporary subgroups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.

**Amendment 550** 

Proposal for a regulation Article 58 – paragraph 10 (new)

Text proposed by the Commission

Amendment

The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available.

**Amendment 551** 

Proposal for a regulation Article 58 a – SECTION 5 – title

Text proposed by the Commission

Amendment

European Authorities on benchmarking

**Amendment 552** 

PE731.563v02-00 280/665 RR\1279290EN.docx

# Proposal for a regulation Article 58 a (new)

Text proposed by the Commission

Amendment

## Article 58 a

# **Benchmarking**

The European authorities on benchmarking referred to in Article 15 (1a) and the AI Office shall, in close cooperation with international partners, jointly develop cost-effective guidance and capabilities to measure and benchmark aspects of AI systems and AI components, and in particular of foundation models relevant to the compliance and enforcement of this Regulation based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards.

## Amendment 553

Proposal for a regulation Article 59 – title

Text proposed by the Commission

Designation of national *competent* authorities

Amendment

Designation of national *supervisory* authorities

#### Amendment 554

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

## Amendment

1. Each Member State shall designate one national supervisory authority, which shall be organised so as to safeguard the objectivity and impartiality of its activities and tasks by ...[three months after the date of entry into force of this Regulation].

RR\1279290EN.docx 281/665 PE731.563v02-00

of *their* activities and tasks.

#### Amendment 555

# 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

**The** national supervisory authority shall 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 administrative procedures. However, to the extent a case involves aspects exclusively covered by this Regulation, those competent authorities shall be bound by the measures related to those aspects issued by the national supervisory authority designated under this Regulation. The national supervisory authority shall act as market surveillance authority.

## **Amendment 556**

# 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 make publicly available and communicate to the AI Office and the Commission the national supervisory authority and information on how it can be contacted, by... [three months after the date of entry into force of this Regulation]. The national supervisory authority shall act as single point of contact for this Regulation and should be contactable though electronic communications means.

# 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 the national supervisory authority is provided with adequate technical, financial and human resources, and infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national supervisory authority 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, cybersecurity, competition law, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if deemed necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

## **Amendment 558**

Proposal for a regulation Article 59 – paragraph 4 a (new)

*Text proposed by the Commission* 

#### Amendment

4 a. Each national supervisory authority shall exercise their powers and carry out their duties independently, impartially and without bias. The members of each national supervisory authority, in the performance of their tasks and exercise of their powers under this Regulation, shall neither seek nor take instructions from any body and shall refrain from any action incompatible with their duties.

# Proposal for a regulation Article 59 – paragraph 4 b (new)

Text proposed by the Commission

## Amendment

4 b. National supervisory authorities shall satisfy the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (EU) 2022/2555.

## **Amendment 560**

Proposal for a regulation Article 59 – paragraph 4 c (new)

Text proposed by the Commission

## Amendment

4 c. When performing their tasks, the national supervisory authority shall act in compliance with the confidentiality obligations set out in Article 70.

## Amendment 561

# 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 *AI Office* for discussion and possible recommendations.

# **Amendment 562**

# 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.

deleted

## **Amendment 563**

# 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

Amendment

7. National *supervisory* authorities may provide guidance and advice on the implementation of this Regulation, including to *SMEs and start-ups, taking into account the AI Office or the Commission's guidance and advice*. Whenever *the* national *supervisory authority* intend to provide guidance and advice with regard to an AI system in areas covered by other Union *law*, the *guidance shall be drafted in consultation with the* competent national authorities under that Union *law*, as appropriate.

# **Amendment 564**

# 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

## **Amendment 565**

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# 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 infringement took place shall be considered the lead supervisory authority.
- 3. In the cases referred to in paragraph 2, the relevant supervisory authorities shall cooperate and exchange all relevant information in due time. National supervisory authorities shall cooperate in order to reach a consensus.

**Amendment 566** 

Proposal for a regulation Title VII

Text proposed by the Commission

Amendment

VII EU DATABASE FOR *STAND-ALONE* HIGH-RISK AI SYSTEMS

EU DATABASE FOR HIGH-RISK AI SYSTEMS

**Amendment 567** 

Proposal for a regulation Article 60 – title

PE731.563v02-00 286/665 RR\1279290EN.docx

EU database for *stand-alone* high-risk AI systems

## Amendment

EU database for high-risk AI systems

## **Amendment 568**

# 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 *paragraphs 2 and 2a* concerning high-risk AI systems referred to in Article *6 (2)* which are registered in accordance with Article 51

## Amendment 569

# 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, **Section A**, shall be entered into the EU database by the providers.

#### Amendment 570

Proposal for a regulation Article 60 – paragraph 2 a (new)

Text proposed by the Commission

## Amendment

2 a. The data listed in Annex VIII, Section B, shall be entered into the EU database by the deployers who are or who

act on behalf of public authorities or Union institutions, bodies, offices or agencies and by deployers who are undertakings referred to in Article 51(1a) and (1b).

## **Amendment 571**

# 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 *freely available* to the public, *user-friendly and accessible*, *easily navigable and machine-readable containing structured digital data based on a standardised protocol*.

## **Amendment 572**

# 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 deployer which is a public authority or Union institution, body, office or agency or a deployer acting on their behalf or a deployer which is an undertaking referred to in Article 51(1a)(b) and (1b).

## **Amendment 573**

PE731.563v02-00 288/665 RR\1279290EN.docx

# 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 deployers* adequate technical and administrative support.

The database shall comply with the accessibility requirements of Annex I to Directive (EU) 2019/882.

## **Amendment 574**

# 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 highrisk 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

The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by deployers or collected through other sources on the performance of highrisk 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. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems environment, including other devices and software taking into account the rules applicable from areas such as data protection, intellectual property rights and competition law.

# **Amendment 575**

# Proposal for a regulation Article 61 – paragraph 3

Text proposed by the Commission

3. The post-market monitoring system

Amendment

3. The post-market monitoring system

RR\1279290EN.docx 289/665 PE731.563v02-00

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.

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 [twelve months after the date of entry into force of this Regulation].

#### Amendment 576

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 577

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 deployers have identified a serious incident, deployers of high-risk AI systems placed on the Union market shall report any serious incident of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the national supervisory authority of the Member States where that incident or breach occurred.

**Amendment 578** 

Proposal for a regulation Article 62 – paragraph 1 – subparagraph 1

PE731.563v02-00 290/665 RR\1279290EN.docx

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, or, where applicable the deployer, has established a causal link between the AI system and the incident or the reasonable likelihood of such a link, and, in any event, not later than 72 hours after the provider or, where applicable, the deployer becomes aware of the serious incident.

## Amendment 579

Proposal for a regulation Article 62 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

1 a. Upon establishing a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, providers shall take appropriate corrective actions pursuant to Article 21.

## Amendment 580

# 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 breach of obligations under Union law intended to protect fundamental rights, the *national supervisory* 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 *by* [the entry into force of this Regulation] and shall be assessed regularly.

## **Amendment 581**

Proposal for a regulation Article 62 – paragraph 2 a (new)

Text proposed by the Commission

#### Amendment

2 a. The national supervisory authority 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 national supervisory authority shall notify the AI Office and the relevant national supervisory authorities of these Member States.

#### **Amendment 582**

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 that constitute a breach of obligations under Union law intended to protect fundamental rights.

#### Amendment

3. For high-risk AI systems referred to in Annex III that are placed on the market or put into service by providers that are subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this Regulation, the notification of serious incidents constituting a breach of fundamental rights under Union law shall be transferred to the national supervisory authority.

#### **Amendment 583**

Proposal for a regulation Article 62 – paragraph 3 a (new)

PE731.563v02-00 292/665 RR\1279290EN.docx

#### Amendment

3 a. National supervisory authorities shall on an annual basis notify the AI Office of the serious incidents reported to them in accordance with this Article.

## **Amendment 584**

# Proposal for a regulation Article 63 – paragraph 1 – introductory part

Text proposed by the Commission

1. Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:

#### Amendment

1. Regulation (EU) 2019/1020 shall apply to AI systems *and foundation models* covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:

## **Amendment 585**

Proposal for a regulation Article 63 – paragraph 1 – point b a (new)

Text proposed by the Commission

#### Amendment

(b a) the national supervisory authorities shall act as market surveillance authorities under this Regulation and have the same powers and obligations as market surveillance authorities under Regulation (EU) 2019/1020.

#### **Amendment 586**

Proposal for a regulation Article 63 – paragraph 2

Text proposed by the Commission

2. The national supervisory authority shall report to the Commission *on a* 

### Amendment

2. The national supervisory authority shall report to the Commission *and the AI* 

regular basis the outcomes of relevant 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.

Office annually the outcomes of relevant 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.

#### Amendment 587

Proposal for a regulation Article 63 – paragraph 3 a (new)

Text proposed by the Commission

#### Amendment

- 3 a. For the purpose of ensuring the effective enforcement of this Regulation, national supervisory authorities may:
- (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.

## **Amendment 588**

# 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

#### 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.

PE731.563v02-00 294/665 RR\1279290EN.docx

competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using those systems.

#### **Amendment 589**

# Proposal for a regulation Article 63 – paragraph 7

Text proposed by the Commission

7. Member States shall facilitate the coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.

#### Amendment

7. **National supervisory** authorities designated under this Regulation **shall coordinate with** other relevant national authorities or bodies which supervise the application of Union harmonisation **law** listed in Annex II or other Union **law** that might be relevant for the high-risk AI systems referred to in Annex III.

### Amendment 590

# 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, and upon their reasoned request the national supervisory authority shall be granted full access to the training, validation and testing datasets used by the provider, or, where relevant, the deployer, that are relevant and strictly necessary for the purpose of its request through appropriate technical means and tools.

## **Amendment 591**

Proposal for a regulation Article 64 – paragraph 2

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

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 including paragraph 1 have been exhausted and have proven to be insufficient, and upon a reasoned request, the *national supervisory authority* shall be granted access to the training and trained models of the AI system, including its relevant model parameters. All information in line with Article 70 obtained shall be treated as confidential information and shall be subject to existing Union law on the protection of intellectual property and trade secrets and shall be deleted upon the completion of the investigation for which the information was requested.

## Amendment 592

Proposal for a regulation Article 64 – paragraph 2 a (new)

Text proposed by the Commission

#### Amendment

2 a. Paragraphs 1 and 2 are without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.

#### **Amendment 593**

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

## Amendment

3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to

PE731.563v02-00 296/665 RR\1279290EN.docx

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.

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 *national supervisory* authority of the Member State concerned of any such request.

#### **Amendment 594**

# 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. National supervisory authorities shall notify the list to the Commission, the AI Office, and all other national supervisory authorities and keep the list up to date. The Commission shall publish in a dedicated website the list of all the competent authorities designated by the Member States in accordance with this Article.

## **Amendment 595**

# 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

#### 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 *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.

Union law intended to protect fundamental rights has occurred, the public authority or body referred to *in* paragraph 3 may make a reasoned request to the *national supervisory* authority, to organise testing of the high-risk AI system through technical means. The *national supervisory* authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

#### Amendment 596

# 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

AI systems presenting a risk shall be understood as an AI system having the potential to affect adversely health and safety, fundamental rights of persons in general, including in the workplace, protection of consumers, the environment, public security, or democracy or the rule of law and other public interests, that are protected by the applicable Union harmonisation law, 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 are concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements.

#### Amendment 597

Proposal for a regulation Article 65 – paragraph 2 – introductory part

Text proposed by the Commission

2. Where the *market surveillance* 

Amendment

2. Where the *national supervisory* 

PE731.563v02-00 298/665 RR\1279290EN.docx

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).

authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, it 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 *national supervisory* authority shall also immediately inform and fully cooperate with 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 vulnerable groups or violates their rights intentionally or unintentionally, the national supervisory authority shall have the duty to investigate the design goals, data inputs, model selection, implementation and outcomes of the AI system. The relevant operators shall cooperate as necessary with the national supervisory authority and the other national public authorities or bodies referred to in Article 64(3);

## **Amendment 598**

# 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 *national supervisory* 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 event no later than fifteen working days or as* 

# provided for in the relevant Union harmonisation law as applicable

## Amendment 599

# Proposal for a regulation Article 65 – paragraph 2 – subparagraph 2

Text proposed by the Commission

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 second subparagraph.

## Amendment

The *national supervisory* authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.

#### Amendment 600

# 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 *national supervisory* authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission, *the AI Office and the national supervisory authority of* 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.

# Amendment 601

# 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

# Amendment

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the *national supervisory* authority shall take all appropriate provisional measures to

PE731.563v02-00 300/665 RR\1279290EN.docx

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.

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 AI Office and the national supervisory authority of* the other Member States of those measures

## **Amendment 602**

# 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 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 *and the supply chain*, 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 *national supervisory authority* shall indicate whether the non-compliance is due to one or more of the following:

#### Amendment 603

# 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 *this Regulation*;

#### **Amendment 604**

# 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;

Amendment 605

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.

**Amendment 606** 

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 *national supervisory* authorities of the Member States other than the *national supervisory* authority of the Member State initiating the procedure shall without delay inform the Commission, *the AI Office* 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 607

Proposal for a regulation Article 65 – paragraph 8

PE731.563v02-00 302/665 RR\1279290EN.docx

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

Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a *national supervisory authority* of a Member State or the Commission in respect of a provisional measure taken by a national supervisory authority of another 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. The period referred to in the first sentence of this paragraph shall be reduced to thirty days in the event of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5.

#### **Amendment 608**

# 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 appropriate restrictive measures are taken in respect of the *product* concerned, such as withdrawal of the *product* from their market, without delay.

# Amendment

9. The *national supervisory* authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the *AI system* concerned, such as withdrawal of the *AI system* from their market, without delay.

# **Amendment 609**

Proposal for a regulation Article 65 – paragraph 9 a (new)

Text proposed by the Commission

## Amendment

9 a. National supervisory authorities shall annually report to the AI Office about the use of prohibited practices that occurred during that year and about the

# measures taken to eliminate or mitigate the risks in accordance with this Article.

## **Amendment 610**

# 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

Where, within three months of 1. 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 the national supervisory authority of a Member State against a measure taken by another *national* supervisory authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the national supervisory authority of 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 three 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 national supervisory authority of the Member State concerned. The Commission shall also inform all other national supervisory authorities of such decision.

**Amendment 611** 

Proposal for a regulation Article 66 – paragraph 2

PE731.563v02-00 304/665 RR\1279290EN.docx

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 *national supervisory authorities designated under this Regulation* shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market *without delay*, and shall inform the Commission *and the AI Office* accordingly. If the national measure is considered unjustified, the *national supervisory authority of the* Member State concerned shall withdraw the measure.

#### Amendment 612

Proposal for a regulation Article 66 a (new)

Text proposed by the Commission

Amendment

## Article 66 a

# Joint investigations

Where a national supervisory authority has reasons to suspect that the infringement by a provider or a deployer of a high-risk AI system or foundation model to this Regulation amount to a widespread infringement with a Union dimension, or affects or is likely affect at least 45 million individuals, in more than one Member State, that national supervisory authority shall inform the AI Office and may request the national supervisory authorities of the Member States where such infringement took place to start a joint investigation. The AI Office shall provide central coordination to the joint investigation. Investigation powers shall remain within the competence of the national supervisory authorities.

#### Amendment 613

# 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 614**

# Proposal for a regulation Article 67 – paragraph 2

Text proposed by the Commission

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.

## **Amendment 615**

#### Amendment

Where, having performed an evaluation under Article 65, in full cooperation with the relevant national public authority referred to in Article 64(3), the national supervisory authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a *serious* risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights, or the environment or the democracy and rule of law 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.

# Amendment

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* authority of the Member State referred to in paragraph 1.

# Proposal for a regulation Article 67 – paragraph 2 a (new)

Text proposed by the Commission

#### Amendment

2 a. Where the provider or other relevant operators fail to take corrective action as referred to in paragraph 2 and the AI system continues to present a risk as referred to in paragraph 1, the national supervisory authority may require the relevant operator to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk.

#### Amendment 616

# 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 *national supervisory authority* shall immediately inform the Commission, *the AI Office* and the other *national supervisory 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.

#### Amendment 617

# 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

# Amendment

4. The Commission, *in consultation* with the AI Office shall without delay enter into consultation with the national supervisory authorities concerned and the

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.

relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the *AI Office* shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

## **Amendment 618**

# 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, in consultation with the AI Office shall immediately communicate its decision to the national supervisory authorities of the Member States concerned and to the relevant operators. It shall also inform the decision to all other national supervisory authorities.

# **Amendment 619**

Proposal for a regulation Article 67 – paragraph 5 a (new)

Text proposed by the Commission

# Amendment

5 a. The Commission shall adopt guidelines to help national competent authorities to identify and rectify, where necessary, similar problems arising in other AI systems.

#### Amendment 620

Proposal for a regulation Article 68 – paragraph 1 – introductory part

Text proposed by the Commission

1. Where the *market surveillance* authority of a Member State makes one of

# Amendment

1. Where the *national supervisory* authority of a Member State makes one of

PE731.563v02-00 308/665 RR\1279290EN.docx

the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:

the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:

#### Amendment 621

# Proposal for a regulation Article 68 – paragraph 1 – point a

Text proposed by the Commission

(a) the *conformity* marking has been affixed in violation of Article 49;

## Amendment

(a) the *CE* marking has been affixed in violation of Article 49;

#### **Amendment 622**

# 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;

## Amendment 623

Proposal for a regulation Article 68 – paragraph 1 – point e a (new)

Text proposed by the Commission

## Amendment

(e a) the technical documentation is not available;

## **Amendment 624**

Proposal for a regulation Article 68 – paragraph 1 – point e b (new)

Text proposed by the Commission

## Amendment

(e b) the registration in the EU database has not been carried out;

RR\1279290EN.docx 309/665 PE731.563v02-00

#### Amendment 625

Proposal for a regulation Article 68 – paragraph 1 – point e c (new)

Text proposed by the Commission

Amendment

(e c) where applicable, the authorised representative has not been appointed.

**Amendment 626** 

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 highrisk 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 *national supervisory authority of the* Member State concerned shall take 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 without delay. The national supervisory authority of the Member State concerned shall immediately inform the AI Office of the non-compliance and the measures taken.

**Amendment 627** 

Proposal for a regulation Article 68 – Chapter 3a (new)

Text proposed by the Commission

Amendment

3 a. Remedies

**Amendment 628** 

Proposal for a regulation Article 68 a (new)

PE731.563v02-00 310/665 RR\1279290EN.docx

Amendment

#### Article 68 a

Right to lodge a complaint with a national supervisory authority

- 1. Without prejudice to any other administrative or judicial remedy, every natural persons or groups of natural persons shall have the right to lodge a complaint with a national supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if they consider that the AI system relating to him or her infringes this Regulation.
- 2. The national supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy pursuant to Article 78.

**Amendment 629** 

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 natural or legal person shall have the right to a an effective judicial remedy

where the national supervisory authority which is competent pursuant to Articles 59 does not handle a complaint or does not inform the data subject within three months on the progress or outcome of the complaint lodged pursuant to Article 68a.

- 3. Proceedings against a national supervisory authority shall be brought before the courts of the Member State where the national supervisory authority is established.
- 4. Where proceedings are brought against a decision of a national supervisory authority which was preceded by an opinion or a decision of the Commission in the union safeguard procedure, the supervisory authority shall forward that opinion or decision to the court.

**Amendment 630** 

Proposal for a regulation Article 68 c (new)

Text proposed by the Commission

Amendment

## Article 68 c

A right to explanation of individual decision-making

1. Any affected person subject to a decision which is taken by the deployer on the basis of the output from an high-risk AI system which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely impact their health, safety, fundamental rights, socio-economic well-being or any other of the rights deriving from the obligations laid down in this Regulation, shall have the right to request from the deployer clear and meaningful explanation pursuant to Article 13(1) on the role of the AI system in the decisionmaking procedure, the main parameters of the decision taken and the related input

PE731.563v02-00 312/665 RR\1279290EN.docx

data.

- 2. Paragraph 1 shall not apply to the use of AI systems for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law are provided in so far as such exception or restrictions respect the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society.
- 3. This Article shall apply without prejudice to Articles 13, 14, 15, and 22 of the Regulation 2016/679.

#### Amendment 631

Proposal for a regulation Article 68 d (new)

Text proposed by the Commission

Amendment

Article 68 d

Amendment to Directive (EU) 2020/1828

In Annex I to Directive (EU) 2020/1828 of the European Parliament and of the Council <sup>1a</sup>, the following point is added:

"(67a) Regulation xxxx/xxxx of the European Parliament and of the Council [laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (OJ L ...)]".

**Amendment 632** 

<sup>&</sup>lt;sup>1a</sup> Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).

# Proposal for a regulation Article 68 e (new)

Text proposed by the Commission

Amendment

## Article 68 e

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.

### Amendment 633

# 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

The Commission, the AI Office and 1. the Member States shall encourage and facilitate the drawing up of codes of conduct intended, including where they are drawn up in order to demonstrate how AI systems respect the principles set out in Article 4a and can thereby be considered trustworthy, to foster the voluntary application to AI systems other than highrisk 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 634**

Proposal for a regulation Article 69 – paragraph 2

Text proposed by the Commission

2 The Commission and the Board

Amendment

2. Codes of *conduct* intended to foster

PE731.563v02-00 314/665 RR\1279290EN.docx

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.

the voluntary compliance with the principles underpinning trustworthy AI systems, shall, in particular:

- (a) aim for a sufficient level of AI literacy among their staff and other persons dealing with the operation and use of AI systems in order to observe such principles;
- (b) assess to what extent their AI systems may affect vulnerable persons or groups of persons, including children, the elderly, migrants and persons with disabilities or whether measures could be put in place in order to increase accessibility, or otherwise support such persons or groups of persons;
- (c) consider the way in which the use of their AI systems may have an impact or can increase diversity, gender balance and equality;
- (d) have regard to whether their AI systems can be used in a way that, directly or indirectly, may residually or significantly reinforce existing biases or inequalities;
- (e) reflect on the need and relevance of having in place diverse development teams in view of securing an inclusive design of their systems;
- (f) give careful consideration to whether their systems can have a negative societal impact, notably concerning political institutions and democratic processes;
- (g) evaluate how AI systems can contribute to environmental sustainability and in particular to the Union's

commitments under the European Green Deal and the European Declaration on Digital Rights and Principles.

#### **Amendment 635**

# 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 both, including with the involvement of users and any interested stakeholders, including scientific researchers, and their representative organisations, in particular trade unions, and consumer organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems. Providers adopting codes of conduct will designate at least one natural person responsible for internal monitoring.

#### **Amendment 636**

# 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 *SMEs* and start-ups when encouraging and facilitating the drawing up of codes of conduct.

## **Amendment 637**

Proposal for a regulation Article 70 – paragraph 1 – introductory part

PE731.563v02-00 316/665 RR\1279290EN.docx

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, national competent authorities and notified bodies, the AI Office and any other natural or legal person 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 638**

# 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 trade secrets of a natural or legal person, in accordance with the provisions of Directives 2004/48/EC and 2016/943/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;

## **Amendment 639**

Proposal for a regulation Article 70 – paragraph 1 – point b a (new) Article 70 paragraphg 1 – point c

Text proposed by the Commission

Amendment

(b a) public and national security interests

# **Amendment 640**

RR\1279290EN.docx 317/665 PE731.563v02-00

# Proposal for a regulation Article 70 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

1 a. The authorities involved in the application of this Regulation pursuant to paragraph 1 shall minimise the quantity of data requested for disclosure to the data that is strictly necessary for the perceived risk and the assessment of that risk. They shall delete the data as soon as it is no longer needed for the purpose it was requested for. They shall put in place adequate and effective cybersecurity, technical and organisational measures to protect the security and confidentiality of the information and data obtained in carrying out their tasks and activities;

## **Amendment 641**

# 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 paragraphs 1 and 1a, 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.

# **Amendment 642**

Proposal for a regulation Article 70 – paragraph 3

PE731.563v02-00 318/665 RR\1279290EN.docx

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States.

#### Amendment

3. Paragraphs 1, *1a* and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States;

#### **Amendment 643**

# 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 *strictly* necessary *and in accordance with relevant provisions of international and trade agreements*, 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 644**

Proposal for a regulation Article 71 – title

Text proposed by the Commission

Penalties and fines

Amendment

**Penalties** 

## Amendment 645

Proposal for a regulation Article 71 – paragraph 1

RR\1279290EN.docx 319/665 PE731.563v02-00

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 by any operator, and shall take all measures necessary to ensure that they are properly and effectively implemented and aligned with the guidelines issued by the Commission and the AI Office pursuant to Article 82b. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into account the interests of SMEs and start-ups and their economic viability;

#### **Amendment 646**

# 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 the Commission and the Office by [12 months after the date of entry into force of this Regulation] of those rules and of those measures and shall notify them, without delay, of any subsequent amendment affecting them.

## **Amendment 647**

# 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 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 40 000 000 EUR or, if the offender is a company, up to 7% of its total worldwide

PE731.563v02-00 320/665 RR\1279290EN.docx

annual turnover for the preceding financial year, whichever is higher:

## **Amendment 648**

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

**Amendment 649** 

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

Amendment 650

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 and 13 shall be subject to administrative fines of up to EUR 20 000 000 or, if the offender is a company, up to 4% of its total worldwide annual turnover for the preceding financial year, whichever is the higher.

**Amendment 651** 

# 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 or foundation model with any requirements or obligations under this Regulation, other than those laid down in Articles 5, 10 and 13, shall be subject to administrative fines of up to EUR 10 000 000 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 652

# 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 5 000 000 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.

## **Amendment 653**

# Proposal for a regulation Article 71 – paragraph 6 – introductory part

Text proposed by the Commission

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:

## Amendment

6. Fines may be imposed in addition to or instead of non-monetary measures such as orders or warnings. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific

PE731.563v02-00 322/665 RR\1279290EN.docx

situation shall be taken into account and due regard shall be given to the following;

#### Amendment 654

# 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 purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;

#### Amendment 655

# 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 *national supervisory* authorities *of one or more Member States* to the same operator for the same infringement;

## **Amendment 656**

# 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 and *annual turnover* of the operator committing the infringement;

#### Amendment 657

Proposal for a regulation Article 71 – paragraph 6 – point c a (new)

RR\1279290EN.docx 323/665 PE731.563v02-00

Amendment

(c a) any action taken by the operator to mitigate the harm of damage suffered by the affected persons;

**Amendment 658** 

Proposal for a regulation Article 71 – paragraph 6 – point c b (new)

Text proposed by the Commission

Amendment

(c b) the intentional or negligent character of the infringement;

**Amendment 659** 

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;

**Amendment 660** 

Proposal for a regulation Article 71 – paragraph 6 – point c d (new)

Text proposed by the Commission

Amendment

(c d) the degree of responsibility of the operator taking into account the technical and organisational measures implemented by them;

**Amendment 661** 

PE731.563v02-00 324/665 RR\1279290EN.docx

## 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 authorities, in particular whether, and if so to what extent, the operator notified the infringement;

## **Amendment 662**

Proposal for a regulation Article 71 – paragraph 6 – point c f (new)

Text proposed by the Commission

Amendment

(c f) adherence to approved codes of conduct or approved certification mechanisms;

## **Amendment 663**

Proposal for a regulation Article 71 – paragraph 6 – point c g (new)

Text proposed by the Commission

Amendment

(c g) any relevant previous infringements by the operator;

## **Amendment 664**

Proposal for a regulation Article 71 – paragraph 6 – point c h (new)

Text proposed by the Commission

Amendment

(c h) any other aggravating or mitigating factor applicable to the circumstances of the case.

#### Amendment 665

## Proposal for a regulation Article 71 – paragraph 7

Text proposed by the Commission

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.

## Amendment

7. each Member State shall lay down rules on administrative fines *to* be imposed on public authorities and bodies established in that Member State;

#### **Amendment 666**

Proposal for a regulation Article 71 – paragraph 8 a (new)

Text proposed by the Commission

## Amendment

8 a. 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 providers and distributors, importers, deployers, or any other third parties;

#### Amendment 667

Proposal for a regulation Article 71 – paragraph 8 b (new)

Text proposed by the Commission

#### Amendment

8 b. National supervisory authorities shall, on an annual basis, report to the AI Office about the fines they have issued during that year, in accordance with this Article;

## **Amendment 668**

PE731.563v02-00 326/665 RR\1279290EN.docx

## Proposal for a regulation Article 71 – paragraph 8 c (new)

Text proposed by the Commission

## Amendment

8 c. The exercise by competent authorities of their powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and national law, including judicial remedy and due process;

#### **Amendment 669**

Proposal for a regulation Article 72 – paragraph 1 – point a

Text proposed by the Commission

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 purpose of the AI system concerned as well as the number of affected persons and the level of damage suffered by them, and any relevant previous infringement;

Amendment 670

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 damage suffered by affected persons;

**Amendment 671** 

Proposal for a regulation Article 72 – paragraph 1 – point a b (new)

#### Amendment

(a b) the degree of responsibility of the Union institution, agency or body, taking into account technical and organisational measures implemented by them;

#### Amendment 672

## Proposal for a regulation Article 72 – paragraph 1 – point b

Text proposed by the Commission

(b) the cooperation with the European Data Protection Supervisor 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 European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;

#### Amendment

(b) the *degree of* cooperation with the European Data Protection Supervisor 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 European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter;

## **Amendment 673**

Proposal for a regulation Article 72 – paragraph 1 – point c a (new) Article 72 paragraph 1 point d – 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 or body notified the infringement;

## Amendment 674

Proposal for a regulation Article 72 – paragraph 1 – point c b (new)

PE731.563v02-00 328/665 RR\1279290EN.docx

Article 72 Paragraph 1 – point e – new

Text proposed by the Commission

Amendment

(c b)the annual budget of the body;

Amendment 675

Proposal for a regulation Article 72 – paragraph 2 – introductory part

Text proposed by the Commission

**The following infringements** shall be subject to administrative fines of up to 500 000 EUR:

Amendment

Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5 shall be subject to administrative fines of up to EUR 1 500 000.

Amendment 676

Proposal for a regulation Article 72 – paragraph 2 – point a

Text proposed by the Commission

Amendment

non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

deleted

Amendment 677

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 1 000 000 EUR.

**Amendment 678** 

## 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 *EUR 750 000*.

## **Amendment 679**

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. *The fines shall not affect the effective operation of the Union institution, body or agency fined.* 

## **Amendment 680**

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 AI Office of the fines it has imposed pursuant to this Article.

**Amendment 681** 

Proposal for a regulation Article 73 – paragraph 2

PE731.563v02-00 330/665 RR\1279290EN.docx

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

The power to adopt delegated acts 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 a period of *five years* from ... [the date of entry into force of the Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

#### Amendment 682

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, the Office, the Advisory Forum and other relevant stakeholders in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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.

**Amendment 683** 

Proposal for a regulation Article 81 a (new)

Amendment

Article 81 a

Amendment to Regulation (EU) 2019/1020

Regulation (EU) 2019/1020 is amended as follows:

in Article 14(4), the following paragraph is added:

"(l). the power to implement the powers provided for in this Article remotely, where applicable;"

**Amendment 684** 

Proposal for a regulation Article 82 a (new)

Text proposed by the Commission

Amendment

Article 82 a

**Better 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.

**Amendment 685** 

Proposal for a regulation Article 82 b (new)

Text proposed by the Commission

Amendment

Article 82 b

Guidelines from the Commission on the implementation of this Regulation

- 1. The Commission shall develop, in consultation with the AI office, guidelines on the practical implementation of this Regulation, and in particular on:
- (a) the application of the requirements referred to in Articles 8 15 and Article 28 to 28b;
- (b) the prohibited practices referred to in Article 5;
- (c) the practical implementation of the provisions related to substantial modification;
- (d) the practical circumstances where the output of an AI system referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons as referred to in Article 6, paragraph 2, including examples in relation to high risk AI systems referred to in Annex III;
- (e) the practical implementation of transparency obligations laid down in Article 52;
- (f) the development of codes of conduct referred to in Article 69;
- (g) the relationship of this Regulation with other relevant Union law, including as regards consistency in their enforcement.
- (h) the practical implementation of Article 12, Article 28b on environmental impact of foundation models and Annex IV 3(b), particularly the measurement and logging methods to enable calculations and reporting of the environmental impact of systems to comply with the obligations in this Regulation, including carbon footprint and energy efficiency, taking into account state-of-the-art methods and economies of scale.

When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, local public authorities and sectors most

likely to be affected by this Regulation.

2. Upon request of the Member States or the AI Office, or on its own initiative, the Commission shall update already adopted guidelines when deemed necessary.

## **Amendment 686**

## 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. 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 prior to ... [the date of entry into force of this Regulation] shall take the necessary steps to comply with the requirements laid down in this Regulation by ... [four years after the date of entry into force of this Regulation].

## **Amendment 687**

## 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 *and whenever* those legal acts are replaced or amended.

## **Amendment 688**

Proposal for a regulation Article 83 – paragraph 2

PE731.563v02-00 334/665 RR\1279290EN.docx

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

This Regulation shall apply to 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)], only if, from that date, those systems are subject to substantial modifications as defined in Article 3(23). In the case of high-risk AI systems intended to be used by public authorities, providers and deployers of such systems shall take the necessary steps to comply with the requirements of the present Regulation [two years after the date of entry into force of this Regulation].

## **Amendment 689**

## 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. After consulting the AI Office, 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 in that Annex.

the list of prohibited AI practices in Article 5, and the list of AI systems requiring additional transparency measures in Article 52 once a year following the entry into force of this Regulation and following a recommendation of the Office.

the Commission shall submit the findings of that assessment to the European Parliament and the Council.

## Amendment 690

# 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 two years thereafter, the Commission, together with the AI office, 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 691**

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;

## **Amendment 692**

Proposal for a regulation Article 84 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) the level of the development of harmonised standards and common specifications for Artificial Intelligence;

## **Amendment 693**

Proposal for a regulation Article 84 – paragraph 3 – point b b (new)

PE731.563v02-00 336/665 RR\1279290EN.docx

Amendment

(b b) the levels of investments in research, development and application of AI systems throughout the Union;

**Amendment 694** 

Proposal for a regulation Article 84 – paragraph 3 – point b c (new)

Text proposed by the Commission

Amendment

(b c) the competitiveness of the aggregated European AI sector compared to AI sectors in third countries;

**Amendment 695** 

Proposal for a regulation Article 84 – paragraph 3 – point b d (new)

Text proposed by the Commission

Amendment

(b d) the impact of the Regulation with regards to the resource and energy use, as well as waste production and other environmental impact;

**Amendment 696** 

Proposal for a regulation Article 84 – paragraph 3 – point b e (new)

Text proposed by the Commission

Amendment

(b e) the implementation of the coordinated plan on AI, taking into account the different level of progress among Member States and identifying existing barriers to innovation in AI;

**Amendment 697** 

## Proposal for a regulation Article 84 – paragraph 3 – point b f (new)

Text proposed by the Commission

Amendment

(b f) the update of the specific requirements regarding the sustainability of AI systems and foundation models, building on the reporting and documentation requirement in Annex IV and in Article 28b;

**Amendment 698** 

Proposal for a regulation Article 84 – paragraph 3 – point b g (new)

Text proposed by the Commission

Amendment

(b g) the legal regime governing foundation models;

Amendment 699

Proposal for a regulation Article 84 – paragraph 3 – point b h (new)

Text proposed by the Commission

Amendment

(b h) the list of unfair contractual terms within Article 28a taking into account new business practices if necessary;

Amendment 700

Proposal for a regulation Article 84 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. By ... [two years after the date of entry into application of this Regulation referred to in Article 85(2)] the Commission shall evaluate the

PE731.563v02-00 338/665 RR\1279290EN.docx

functioning of the AI office, whether the office has been given sufficient powers and competences to fulfil its tasks and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the Office and its enforcement competences and to increase its resources. The Commission shall submit this evaluation report to the European Parliament and to the Council.

## Amendment 701

## 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 702**

## 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

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;

## 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 *without undue delay*.

#### **Amendment 703**

## 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 -AI Office of the European Parliament, of the Council, and of other relevant bodies or sources and shall consult relevant stakeholders. The result of such consultation shall be attached to the report;

#### Amendment 704

# 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, democracy and rule of law and in the light of the state of progress in the information society.

## **Amendment 705**

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 of this Article, the Office shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the

PE731.563v02-00 340/665 RR\1279290EN.docx

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 in that Annex; the list of prohibited practices laid down in Article 5; and the list of AI systems requiring additional transparency measures pursuant to Article 52.

**Amendment 706** 

Proposal for a regulation Article 84 – paragraph 7 b (new)

Text proposed by the Commission

#### Amendment

7 b. Any amendment to this Regulation pursuant to paragraph 7 of this Article, or relevant future delegated or implementing acts, which concern sectoral legislation listed in Annex II Ssection B, shall take into account the regulatory specificities of each sector, and existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

Amendment 707

Proposal for a regulation Article 84 – paragraph 7 c (new)

Text proposed by the Commission

#### Amendment

7 c. By ... [five years from the date of application of this Regulation], 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 Union agency to resolve any identified shortcomings.

#### **Amendment 708**

## Proposal for a regulation Annex I

Text proposed by the Commission

Amendment

# ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES referred to in Article 3, point 1

- (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.

deleted

## Amendment 709

## Proposal for a regulation Annex III – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:

The AI systems specifically refered to in under points 1 to 8a stand for critical use cases and are each considered to be high-risk AI systems pursuant to Article 6(2), provided that they fulfil the criteria set out in that Article:

#### Amendment 710

## 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 and biometrics-based systems

## **Amendment 711**

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;
- (a) AI systems intended to be used for biometric identification of natural persons, with the exception of those mentioned in Article 5:

## **Amendment 712**

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 about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems, with the exception of those mentioned in Article 5;

Point 1 shall not include AI systems intended to be used for biometric verification whose sole purpose is to confirm that a specific natural person is the person he or she claims to be.

## Amendment 713

## 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, *rail and air* traffic *unless they are regulated in harmonisation or sectoral law*.

## Amendment 714

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 components in the management and operation of the supply of water, gas, heating, electricity and critical digital infrastructure;

#### Amendment 715

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 intended to be used for the purpose of determining access *or materially influence decisions on admission* or assigning natural persons to educational and vocational training institutions;

## **Amendment 716**

Proposal for a regulation Annex III – paragraph 1 – point 3 – point b

PE731.563v02-00 344/665 RR\1279290EN.docx

(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:

## **Amendment 717**

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 purpose of assessing the appropriate level of education for an individual and materially influencing the level of education and vocational training that individual will receive or will be able to access;

#### **Amendment 718**

Proposal for a regulation Annex III – paragraph 1 – point 3 – point b b (new)

Text proposed by the Commission

Amendment

(b b) AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests in the context of/within education and vocational training institutions;

**Amendment 719** 

Proposal for a regulation Annex III – paragraph 1 – point 4 – point a

(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, notably for *placing targeted job advertisements* screening or filtering applications, evaluating candidates in the course of interviews or tests:

## Amendment 720

## 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 to make or materially influence decisions affecting the initiation, promotion and termination of work-related contractual relationships, task allocation based on individual behaviour or personal traits or characteristics, or for monitoring and evaluating performance and behavior of persons in such relationships;

## **Amendment 721**

## 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 or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, including healthcare services and essential services, including but not limited to housing, electricity, heating/cooling and internet, as well as to grant, reduce, revoke, increase or reclaim such benefits and services;

PE731.563v02-00 346/665 RR\1279290EN.docx

#### Amendment 722

## 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 *used for the purpose of detecting financial fraud;* 

## **Amendment 723**

Proposal for a regulation Annex III – paragraph 1 – point 5 – point b a (new)

Text proposed by the Commission

Amendment

(b a) AI systems intended to be used for making decisions or materially influencing decisions on the eligibility of natural persons for health and life insurance;

## Amendment 724

## Proposal for a regulation Annex III – paragraph 1 – point 5 – point c

Text proposed by the Commission

(c) AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid.

## Amendment

(c) AI systems intended to evaluate and classify emergency calls by natural persons or to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by police and law enforcement, firefighters and medical aid, as well as of emergency healthcare patient triage systems;

## **Amendment 725**

## 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

## **Amendment 726**

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;*
- (b) AI systems intended to be used by or on behalf of law enforcement authorities, or by Union agencies, offices or bodies in support of law enforcement authorities as polygraphs and similar tools, insofar as their use is permitted under relevant Union and national law;

**Amendment 727** 

Proposal for a regulation Annex III – paragraph 1 – point 6 – point c

Text proposed by the Commission

Amendment

(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

deleted

**Amendment 728** 

Proposal for a regulation Annex III – paragraph 1 – point 6 – point d

PE731.563v02-00 348/665 RR\1279290EN.docx

(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 or on behalf of law enforcement authorities, or by Union agencies, offices or bodies in support of law enforcement authorities to evaluate the reliability of evidence in the course of investigation or prosecution of criminal offences;

## **Amendment 729**

Proposal for a regulation Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

(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;

Amendment

deleted

## Amendment 730

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 or on behalf of law enforcement authorities or by Union agencies, offices or bodies in support 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, in the case of Union agencies, offices or bodies, as referred to in Article 3(5) of Regulation (EU) 2018/1725;

## **Amendment 731**

## 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 or on behalf of law enforcement authorities or by Union agencies, offices or bodies in support of law enforcement authorities 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 732

## 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 or on behalf of competent public authorities or by Union agencies, offices or bodies as polygraphs and similar tools insofar as their use is permitted under relevant Union or national law

#### Amendment 733

## 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 or on behalf of competent public authorities or by Union agencies, offices or bodies to assess a risk, including a

PE731.563v02-00 350/665 RR\1279290EN.docx

posed by a natural person who intends to enter or has entered into the territory of a Member State: 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 734

## 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 or on behalf of competent public authorities or by Union agencies, offices or bodies 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 735

## 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 or on behalf of competent public authorities or by Union agencies, offices or bodies to assist competent public authorities for the examination and assessment of the veracity of evidence 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;

## **Amendment 736**

Proposal for a regulation Annex III – paragraph 1 – point 7 – point d a (new)

RR\1279290EN.docx 351/665 PE731.563v02-00

## Amendment

(d a) AI systems intended to be used by or on behalf of competent public authorities or by Union agencies, offices or bodies in migration, asylum and border control management to monitor, surveil or process data in the context of border management activities, for the purpose of detecting, recognising or identifying natural persons;

## **Amendment 737**

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 public authorities or by Union agencies, offices or bodies in migration, asylum and border control management for the forecasting or prediction of trends related to migration movement and border crossing;

## **Amendment 738**

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 ot administrative body or on their behalf to assist a judicial authority or administrative body in researching and interpreting facts and the law and in applying the law to a concrete set of facts or used in a similar way in alternative dispute resolution.

## Amendment 739

PE731.563v02-00 352/665 RR\1279290EN.docx

## 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 for influencing the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda. This does not include AI systems whose output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistic point of view.

#### Amendment 740

Proposal for a regulation Annex III – paragraph 1 – point 8 – point a b (new)

Text proposed by the Commission

Amendment

(a b) AI systems intended to be used by social media platforms that have been designated as very large online platforms within the meaning of Article 33 of Regulation EU 2022/2065, in their recommender systems to recommend to the recipient of the service user-generated content available on the platform.

## **Amendment 741**

version of the system;

(a)

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

its intended purpose, the *person/s* developing the system the date and the

Amendment

(a) its intended purpose, the *name of* the provider and the version of the system reflecting its relation to previous and, where applicable, more recent, versions in the succession of revisions;

#### Amendment 742

## Proposal for a regulation Annex IV – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) the nature of data likely or intended to be processed by the system and, in the case of personal data, the categories of natural persons and groups likely or intended to be affected;

## **Amendment 743**

## 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 *can interact* 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;

#### Amendment 744

## 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, where applicable, information for the deployer on any requirement related to version update;

## **Amendment 745**

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point d

PE731.563v02-00 354/665 RR\1279290EN.docx

## Amendment

(d) the description of *all forms in which* the AI system *is* placed on the market or put into service;

(d) the description of *the various* configurations and variants of the AI system which are intended to be placed on the market or put into service;

#### Amendment 746

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point f a (new)

Text proposed by the Commission

Amendment

(f a) the description of the deployer interface;

## **Amendment 747**

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point g

Text proposed by the Commission

Amendment

- (g) instructions of use for the *user* and, where applicable installation instructions;
- (g) instructions of use for the *deployer* in accordance with Article 13(2) and (3) as well as 14(4)(e) and, where applicable installation instructions;

#### Amendment 748

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point g a (new)

Text proposed by the Commission

Amendment

(g a) a detailed and easily intellegible description of the system's main optimisation goal or goals;

## Amendment 749

## Proposal for a regulation Annex IV – paragraph 1 – point 1 – point g b (new)

Text proposed by the Commission

Amendment

(g b) a detailed and easily intellegible description of the system's expected output and expected output quality;

## Amendment 750

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point g c (new)

Text proposed by the Commission

Amendment

(g c) detailed and easily intellegible instructions for interpreting the system's output;

## **Amendment 751**

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point g d (new)

Text proposed by the Commission

Amendment

(g d) examples of scenarios for which the system should not be used;

#### Amendment 752

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

Amendment

(b) a description of the architecture, design specifications, algorithms and the data structures including 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

PE731.563v02-00 356/665 RR\1279290EN.docx

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; 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 753

## Proposal for a regulation Annex IV – paragraph 1 – point 2 – point c

Text proposed by the Commission

(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;

## Amendment

(c) deleted

## Amendment 754

## 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);

## **Amendment 755**

Proposal for a regulation Annex IV – paragraph 1 – point 2 – point g

(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 accuracy, robustness 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 756

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.

## **Amendment 757**

Proposal for a regulation Annex IV – paragraph 1 – point 3

Text proposed by the Commission

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

## 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

PE731.563v02-00 358/665 RR\1279290EN.docx

view of the intended purpose 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;

view of the intended purpose 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 *deployers*; specifications on input data, as appropriate;

#### Amendment 758

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;

## **Amendment 759**

Proposal for a regulation Annex IV – paragraph 1 – point 3 b (new)

Text proposed by the Commission

Amendment

3 b. Information about the energy consumption of the AI system during the development phase and the expected energy consumption during use, taking into account, where applicable, relevant Union and national law;

## Amendment 760

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 *by providers* to the system through its *lifecycle*;

#### Amendment 761

## 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 other relevant standards *or common* specifications applied;

#### **Amendment 762**

Proposal for a regulation Annex V – paragraph 1 – point 4 a (new)

Text proposed by the Commission

## Amendment

4 a. Where an AI system involves the processing of personal data, a statement that that AI system complies with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680.

## Amendment 763

Proposal for a regulation Annex V – paragraph 1 – point 7

Text proposed by the Commission

7. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

## Amendment

7. Place and date of issue of the declaration, *signature*, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

## Amendment 764

PE731.563v02-00 360/665 RR\1279290EN.docx

## 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 *training* and trained models of the AI system. including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets. They shall take technical and organisational measures to ensure the protection of intellectual property and trade secrets.

## Amendment 765

## 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

**Section A** - 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 (1).

## **Amendment 766**

Proposal for a regulation Annex VIII – point 4 a (new)

Text proposed by the Commission

## Amendment

4 a. Foundation model trade name and any additional unambiguous refernce allowing identification and traceability

## Amendment 767

## 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. A simple and comprehensible description of
- **a.** the intended purpose of the AI system;
- b. the components and functions supported through AI;
- c. a basic explanation of the logic of the AI system

## **Amendment 768**

Proposal for a regulation Annex VIII – point 5 a (new)

Text proposed by the Commission

Amendment

5 a. where applicable, the categories and nature of data likely or foreseen to be processed by the AI system.

**Amendment 769** 

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

**Amendment 770** 

PE731.563v02-00 362/665 RR\1279290EN.docx

## Proposal for a regulation ANNEX VIII – SECTION B (new)

Text proposed by the Commission

#### Amendment

- SECTION B 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 (1a) (a) and (1b).
- 1. the name, address and contact details of the deployer;
- 2. the name, address and contact details of the person submitting information on behalf of the deployer;
- 3. the high risk AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system used;
- 4. a) A simple and comprehensible description of the intended use of the AI system, including the specific outcomes sought through the use of the systemn, the geographic and temporal scope of application
- b. Where applicable, the categories and nature of data to be processed by the AI system;
- c. Arrangements for human oversight and governance
- d. Where relevant, the bodies or natural persons responsible for decisions taken or supported by the AI system;
- 5. a summary of the findings of the fundamental rights impact assessment conducted in accordance with Article 29a
- 6. The URL of the entry of the AI system in the EU database by its provider
- 7. 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

RR\1279290EN.docx 363/665 PE731.563v02-00

## applicable.

#### Amendment 771

## Proposal for a regulation Annex VIII – Section C (new)

Text proposed by the Commission

### Amendment

Section C - The following information shall be provided and thereafter kept up to date with regard to foundation models to be registered in accordance with Article 28b (e).

- 1. Name, address and contact details of the provider;
- 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;
- 3. Name, address and contact details of the authorised representative, where applicable;
- 4. Trade name and any additional unambiguous reference allowing the identification of the foundation model
- 5. Description of the data sources used in the development of the foundational model
- 6. Description of the capabilities and limitations of the foundation model, including the reasonably foreseeable risks and the measures that have been taken to mitigate them as well as remaining non-mitigated risks with an explanation on the reason why they cannot be mitigated
- 7. Description of the training resources used by the foundation model including computing power required, training time, and other relevant information related to the size and power of the model 8. Description of the model's performance, including on public benchmarks or state of the art industry benchmarks

- 8. Description of the results of relevant internal and external testing and optimisation of the model
- 9. Member States in which the foundation model is or has been placed on the market, put into service or made available in the Union;
- 10. URL for additional information (optional).

## **EXPLANATORY STATEMENT**

The co-Rapporteurs share the view that artificial intelligence developed and used in Europe should be human-centric and trustworthy and should respect fundamental rights and Union values enshrined in the Treaties. At the same time, regulation should not hinder but, rather, it should support innovation and the business environment. Both of these objectives are best achieved by increasing legal certainty and clarity throughout the Regulation proposal, in order to support the private sector and public authorities to comply with the new obligations. The draft Report contains the points on which the co-Rapporteurs could easily agree, and it touches upon all the main elements of the draft Regulation.

In terms of scope, the co-rapporteurs agree with the risk-based approach proposed by the Commission. That is, the obligations set out in this Regulation only apply to forbidden practices, to high-risk AI systems, and to certain AI systems that require transparency. As such, no AI system should be excluded ex-ante, either from the definition of "artificial intelligence" or by carving out exceptions for particular types of AI systems, including general purpose AI. Where, for objective reasons, providers are unable to fulfil the obligations under this Regulation, they should be able to enter into agreements with the users to share the responsibilities. A key element of the draft Report is also the alignment of the text with the GDPR, as the two regulations should work complementary to one another for the development and uptake of AI in Europe.

In terms of forbidden practices, the co-rapporteurs have agreed to add practices that amount to "predictive policing" to the list, as they share the view that liberal societies cannot use technology in breach of the key principle of presumption of innocence.

As regards high-risk AI systems, which are the main focus of the Regulation, the co-Rapporteurs propose adding a number of use cases to the list of high-risk AI systems. As children are a particularly vulnerable category, AI systems used to influence or shape their development should be considered high risk. AI systems used by candidates or parties to influence votes in local, national, or European elections, and AI systems used to count such votes, have the potential, by influencing a large number of citizens of the Union, to impact the very functioning of our democracy. They should therefore be considered high risk. AI systems used for the triage of patients in the healthcare sector, and AI systems used to determine eligibility for health and life insurance are also considered high-risk. Because of their potential for deception, two types of AI systems should be subject to both transparency requirements and the conformity requirements of high-risk AI systems: deepfakes impersonating real persons and editorial content written by AI ("AI authors"). The corapporteurs stress that high-risk AI systems are not prohibited, nor are they to be seen as undesirable. To the contrary, complying with the conformity requirements set out in this Regulation makes such systems more trustworthy and more likely to be successful on the European market.

The draft Report considers more closely the chain of responsibility and tries to clarify and rebalance some provisions. Namely, on data governance, the consistency with GDPR has been strengthened and the possible additional legal basis for processing personal data has been removed. In addition, it has been clarified that "error-free" datasets should be an overall objective to reach to the best extent possible, rather than a precise requirement. The cases of

PE731.563v02-00 366/665 RR\1279290EN.docx



datasets being in the possession of users, while the provider only build the overall architecture of the system, have also been clarified. Most of these clarifications take into account concerns expressed by industry, as the AI value chain is not always linear and responsibilities need to be clearly delineated between different actors in the value chain.

Users of high-risk AI systems also play a role in protecting the health, safety, and fundamental rights of EU citizens and EU values, from ensuring that they appoint competent persons responsible for the human oversight of high-risk AI systems to playing a more active role in reporting cases of incidents or malfunctioning of an AI system, as they are sometimes best placed to spot such incidents or malfunctions. Users who are public authorities are subject to increased transparency expectations in democratic societies. As such, public authorities, Union institutions, agencies, or bodies should register the use of high-risk AI systems in the EU-wide database. This allows for increased democratic oversight, public scrutiny, and accountability, alongside more transparency towards the public on the use of AI systems in sensitive areas impacting upon people's lives. Additionally, users of high-risk AI systems referred to in Annex III that make decisions or that assist in making decisions related to natural persons should inform the natural persons that they are subject to the use of the high-risk AI system.

Several provisions of the draft Report focus on governance and enforcement, as the co-Rapporteurs are convinced these are key elements to allow the AI Act to be implemented effectively and consistently throughout the Union and therefore help create a true Single Market for AI.

To this end, the tasks of the AI Board have been increased. The AI Board should play a more significant role in the uniform application of the Regulation and in providing advice and recommendations to the Commission, for example on the need to amend Annex III, and to national supervisory authorities. The Board should act as a forum for exchange among national supervisory authorities and, at the same time, it should constitute a place for arbitration of disputes involving two or more Member States' authorities, in order to avoid the fragmentation of the Single Market through differentiated enforcement. Furthermore, given its increased role and responsibilities, the Board should organize, at least twice a year, consultations with industry, start-ups and SMEs, civil society, and academia, in order to carry out its tasks in collaboration with all relevant stakeholders.

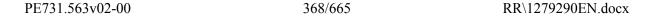
At the national level, the co-Rapporteurs have stressed the need for close cooperation between the market surveillance authorities and the data protection authorities, as the enforcement of the Regulation on AI will require both sets of competences, which, moreover, should be regularly updated. In cases of infringements on fundamental rights, the relevant fundamental rights bodies should also be closely involved.

In order to tackle possible issues impacting individuals in several Member States, the co-Rapporteurs propose a new enforcement mechanism by the Commission, to be triggered in cases amounting to widespread infringements (three or more Member States), including in the case of inaction on an infringement impacting at least three Member States. This mechanism, based on the model of the Digital Services Act but adapted to the different nature of the AI legislation, aims to address some of the enforcement problems that have been observed in other governance setups, to contribute to the uniform implementation of this regulation, and to strengthen the digital single market. According to the mechanism, in such cases of widespread infringements, the Commission should have the powers of a market surveillance

authority, on the model of the Market Surveillance and compliance Regulation.

The co-Rapporteurs believe it is important to strengthen the involvement of stakeholders and civil society organizations in several key provisions of the Regulation, such as the updates to the list of high-risk AI systems, the standardization process, as well as the activities of the Board and the sandboxes. Furthermore, in order to ensure that individuals are properly empowered when the use of an AI system infringes on their rights, but also in order to contribute to building trust in AI systems and their widespread use, the co-rapporteurs have added a dedicated chapter on remedies for both natural and legal persons.

The co-rapporteurs want to emphasize, together, that the goal of the AI Act is to ensure both the protection of health, safety, fundamental rights, and Union values and, at the same time, the uptake of AI throughout the Union, a more integrated digital single market, and a legislative environment suited for entrepreneurship and innovation. This spirit has guided and will continue to guide their work on this Regulation.



## OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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

on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts

(COM(2021)0206 - C9-0146/2021 - 2021/0106(COD))

Rapporteur for opinion (\*): Eva Maydell(\*) Associated committee – Rule 57 of the Rules of Procedure

## SHORT JUSTIFICATION

### Introduction

The Rapporteur welcomes the Commission's proposal on an Artificial Intelligence Act and especially the horizontal risk-based approach that it puts forward. This approach will allow for the development of AI systems in line with European values and for the fostering of social trust in these new technologies, so that the EU can fulfil the full economic and social benefits of AI.

The Rapporteur is of the opinion that through the AI Act, we need to create an environment with the right balance between freedom and supervision. The Rapporteur proposes that further provisions are made in order for companies, especially start-ups and SMEs, to remain competitive and creative in the face of new obligations required of them. The Rapporteur believes this will increase both the legitimacy and relevance of the AI Act. We need to provide companies with clearer guidelines, simpler tools and more efficient resources to cope with regulation. This would allow us to support AI innovation, development and market uptake.

Therefore, the Rapporteur's draft pursues four main objectives in this direction:

- 1. Enhancing measures to support innovation, such as the ones foreseen for regulatory sandboxes, with a particular focus on start-ups and SMEs
- 2. Providing a concise and internationally recognised definition of Artificial Intelligence System and setting high but realistic standards for accuracy, robustness, cybersecurity and data
- 3. Encouraging the uptake of AI systems by industry by placing an emphasis on social trust and value chain responsibility
- 4. Future-proofing the Act through better linkages to the green transition and possible changes in the industry, technology and power of AI

This draft opinion focuses mainly on issues related to ITRE's competences but also broader issues related to innovation, competitiveness, research, sustainability and future changes in industry.

Supporting innovation, focus on start-ups and SMEs, enhancing regulatory sandboxes

The Rapporteur welcomes the introduction of Article 55 on measures for small-scale providers, but believes SMEs and start-ups should be more involved throughout the AI Act in a holistic approach. More specifically, in the development of Codes of Conduct, standardisation, and representation in the European Artificial Intelligence Board. By far, one of the biggest focuses for the Rapporteur is the provision of opportunities to SMEs and start-ups to participate in the AI regulatory sandboxes. This is why the Rapporteur proposes to strengthen the existing provisions by giving the regulatory sandboxes a more European dimension, preserving the unity of the Single Market and calling for the development of an EU AI Regulatory Sandboxing Programme whose modalities are set out in a new Annex.

## Clear definition and realistic standards

The Rapporteur calls for the use of an internationally recognised definition of Artificial Intelligence System, which would be in line with the EU's broader goals of setting global standards, working closely with transatlantic partners and likeminded allies and providing legal certainty for businesses, citizens and civil society. The Rapporteur believes that high standards for accuracy, robustness and cybersecurity as well as data and data governance are key to developing safe AI systems that protect fundamental rights. The key here is to balance this aim with the practical and pragmatic approach needed for achieving it. The Rapporteur calls for a common European authority on benchmarking that brings together national metrology and benchmarking authorities to set a unified approach to measurement of accuracy, robustness, and other relevant criteria.

Encouraging uptake of AI systems, fostering social trust, value chain responsibility To encourage uptake and deployment of AI systems, the Rapporteur believes we need to foster social trust of both businesses and citizens. The Rapporteur seeks to address the challenge of social trust by encouraging a collaborative relationship between developers and users of AI that is better aligned to their responsibilities along the value chain, strengthening the Codes of Conduct and enhancing the measures on regulatory sandboxes to enable compliance-by-design. This in turn creates a healthy and integrated ecosystem, which will help reduce legal uncertainty and implementation gaps, all of which in turn will increase social trust.

Future-proofing, sustainability and changes in the industry and power of AI

AI is a mature and ready-to-use technology that can be used to process the ever growing amount of data created along industrial processes. To facilitate investments to AI-based analysis and optimisation solutions, this regulation should provide a predictable environment for low-risk industrial solutions. Furthermore, this Regulation should take into account future changes in the industry and power of AI. This is why the Rapporteur proposes great involvement of the High Level Expert Group on AI with both the Commission and the European Artificial Intelligence Board as well as the monitoring of market trends and foresight by the European AI Board.

## **AMENDMENTS**

The Committee on Industry, Research and Energy calls on the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home

Affairs, as the committees responsible, to take into account the following amendments:

#### Amendment 1

Proposal for a regulation Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a)Furthermore, in order for the Member States to reach their climate targets and to meet the United Nation's Sustainable Development Goals (SDGs), Union companies should be encouraged to utilise available technological advancements in realising this goal. AI is a well-developed and ready-to-use technology that can be used to process ever-growing amount of data created along industrial processes. To facilitate investments in AI-based analysis and optimisation solutions that can help to achieve the climate goals, this Regulation should provide a predictable and proportionate environment for low-risk industrial solutions. To ensure coherence, this requires that AI systems themselves need to be designed sustainably to reduce resource usage and energy consumption, thereby limiting the damage to the environment.

## **Amendment 2**

Proposal for a regulation Recital 3 b (new)

Text proposed by the Commission

Amendment

(3b) 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 and SMEs. Special attention should be paid to ensuring that the benefits of artificial intelligence 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.

#### Amendment 3

## Proposal for a regulation Recital 6

Text proposed by the Commission

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 standalone 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

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 been accepted internationally. The definition should be based on the key functional characteristics of the AI system, in particular the ability, for a given set of human-defined objectives, to make predictions, recommendations, or decisions influencing real or virtual environments. More specifically, the definition of AI system should take into account key features such as the ability to perceive real and/or virtual environments, to abstract such perceptions into models through analysis in an automated manner and to use model inference to formulate options for information or action. AI systems are 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

PE731.563v02-00 372/665 RR\1279290EN.docx

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. While drafting these delegated acts, the Commission should insure the input of all relevant stakeholders including the technical experts and developers of AI systems. This consultation could 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. Furthermore, the Commission should engage in dialogue with key international organisations such as the Organisation for Economic Cooperation and Development and other key organisations working on the definition of AI systems to ensure alignment between definitions of AI, while keeping the prerogative of the Union to set its own definition and standards through enacting legislation.

## Amendment 4

Proposal for a regulation Recital 12 a (new)

Text proposed by the Commission

Amendment

(12a) This Regulation should not undermine research and development activity and should respect freedom of science. It is therefore necessary to ensure that this Regulation does not otherwise affect scientific research and development activity on AI systems. As regards product oriented research activity by providers, this Regulation should apply insofar as such research leads to or entails placing 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.

## Amendment 5

## Proposal for a regulation Recital 29

Text proposed by the Commission

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 Council<sup>39</sup>, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>40</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>41</sup>, Directive 2014/90/EU of the European Parliament and of the Council<sup>42</sup>, Directive (EU) 2016/797 of the European Parliament and of the Council<sup>43</sup>, Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>44</sup>, Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>45</sup>, and Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>46</sup>, 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

As regards high-risk AI systems (29)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 Council<sup>39</sup>, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>40</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>41</sup>. Directive 2014/90/EU of the European Parliament and of the Council<sup>42</sup>, Directive (EU) 2016/797 of the European Parliament and of the Council<sup>43</sup>, Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>44</sup>, Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>45</sup>, and Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>46</sup>, 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. In addition, effective standardisation rules are needed to make the requirements of this Regulation operational. The Union's institutions, in particular the Commission, should, together with enterprises, identify the AI

PE731.563v02-00 374/665 RR\1279290EN.docx

sectors where there is the greatest need for standardisation, to avoid fragmentation of the market and maintain and further strengthen the integration of the European Standardisation System (ESS) within the International Standardisation System (ISO, IEC).

<sup>&</sup>lt;sup>39</sup> 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).

<sup>&</sup>lt;sup>40</sup> 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).

<sup>&</sup>lt;sup>41</sup> 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).

<sup>&</sup>lt;sup>42</sup> 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).

<sup>&</sup>lt;sup>43</sup> 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).

<sup>&</sup>lt;sup>44</sup> 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,

<sup>&</sup>lt;sup>39</sup> 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).

<sup>&</sup>lt;sup>40</sup> 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).

<sup>&</sup>lt;sup>41</sup> 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).

<sup>&</sup>lt;sup>42</sup> 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).

<sup>&</sup>lt;sup>43</sup> 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).

<sup>&</sup>lt;sup>44</sup> 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).

<sup>45</sup> 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).

<sup>46</sup> 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).

14.6.2018, p. 1).

<sup>45</sup> 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).

<sup>46</sup> 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).

## **Amendment 6**

Proposal for a regulation Recital 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 *shouldbe* 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 highrisk AI systems.

High data quality is essential for the (44)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 are designed with the best possible efforts to ensure that they are relevant, representative, free of errors and appropriately vetted for errors 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, with specific attention to the mitigation of possible biases in the datasets, that might lead to risks to fundamental rights or discriminatory outcomes for the persons affected by the high-risk AI system. 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, contextual or functional setting or context within which the AI system is intended to be used, with specific attention to women, vulnerable groups and children. 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.

### Amendment 7

## Proposal for a regulation Recital 46

Text proposed by the Commission

Having information on how highrisk 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 *comprehensible* 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 and to allow users to make informed and autonomous decisions about their use. 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 8

## 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 and cybersecurity in accordance with the generally acknowledged state of the art. Accuracy metrics and their expected level should be defined with the primary objective to mitigate risks and negative impact of the AI system to individuals and the society as a whole. The expected level of accuracy and accuracy metrics should be communicated in a clear, transparent,

PE731.563v02-00 378/665 RR\1279290EN.docx

easily understandable and intelligible way to the users. The declaration of accuracy metrics cannot however be considered proof of future levels but relevant methods need to be applied to ensure sustainable levels during use. 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 non-binding guidance to address the technical aspects of to how to measure the appropriate levels of accuracy and robustness.

## Amendment 9

## 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 outputs generated by the AI system.

### Amendment

(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 outputs generated by the AI system. Users of the AI system should take steps to ensure that the possible trade-off between robustness and accuracy does not lead to discriminatory or negative outcomes for minority subgroups.

## **Amendment 10**

## 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

Cybersecurity plays a crucial role in (51)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 confidentiality 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. High-risk AI should be accompanied by security solutions and patches for the lifetime of the product, or in case of the absence of dependence on a specific product, for a time that needs to be stated by the manufacturer.

## **Amendment 11**

## 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 Council<sup>54</sup> should be a means for

### 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 Council<sup>54</sup> should be a means for

PE731.563v02-00 380/665 RR\1279290EN.docx

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.

providers to demonstrate conformity with the requirements of this Regulation. *In* addition to technical details, the standardisation process should also take into account risks to fundamental rights, the environment, and society as a whole and other democratic and sociotechnical aspects of the AI system, and should ensure that the relevant subject-matter experts are included and consulted in the standardisation process. The standardisation process should be transparent in terms of legal and natural persons participating in the standardisation activities. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient. In developing these common specifications Commission should involve views of relevant stakeholders, in particular when the common specifications address specific fundamental rights concerns. In particular, the Commission should adopt common specifications setting out how risk management systems give specific consideration to impact on children.

### Amendment 12

<sup>54</sup> 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).

Standardisation (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).

## 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 and ethically justified 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 and make such regulatory sandboxes widely available throughout the Union, in order 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. Any significant risks 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.

### Amendment 13

## 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

## 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

PE731.563v02-00 382/665 RR\1279290EN.docx

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.

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 and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups; to contribute to achieving the targets on AI as set in the Policy Programme "Path to the Digital Decade"; to contribute to the development of ethical, socially responsible and environmentally sustainable AI systems; to permit effective participation of SMEs and start-ups in regulatory sandboxes, compliance costs should be kept to a reasonable level to ensure the development of trustworthy European artificial intelligence solutions; 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, while encouraging innovation. 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 14

# Proposal for a regulation Recital 72 a (new)

Text proposed by the Commission

#### Amendment

(72a) It is desirable for the establishment of regulatory sandboxes, which is at present left to the discretion of Member States, as a next step to be made obligatory, with properly established criteria, to ensure both the effectiveness of the AI system and easier access for enterprises, in particular SMEs. Research enterprises and institutions should be involved in developing the conditions for the creation of regulatory sandboxes.

## **Amendment 15**

## 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

## 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 AI literacy, awareness raising and information communication. Member States should utilise existing channels and where appropriate, establish new dedicated channels for communication with SMEs, start-ups, users and other innovators to provide guidance and respond to queries about the implementation of this

PE731.563v02-00 384/665 RR\1279290EN.docx

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.

Regulation. Such existing channels could include, inter alia, ENISA's Computer Security Incident Response Teams, National Data Protection Agencies, the AI-on demand platform, the European Digital Innovation Hubs and other relevant instruments funded by EU programmes as well as the Testing and Experimentation Facilities established by the Commission and the Member States at national or Union level. Where appropriate, these channels should work together to create synergies and ensure homogeneity in their guidance to startups, SMEs and users. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. The Commission should regularly assess the certification and compliance costs for SMEs and start-ups, including through transparent consultations with SMEs, start-ups and users and work with Member States to lower such costs. For example, 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. Medium-sized enterprises which recently changed from the small to medium-size category within the meaning of Recommendation 2003/361/EC should have access to these initiatives and guidance for a period of time deemed appropriate by the Member States, as these new medium-sized enterprises may sometimes lack the legal resources and training necessary to ensure proper understanding and compliance with provisions.

## **Amendment 16**

# Proposal for a regulation Recital 76 a (new)

Text proposed by the Commission

### Amendment

(76a) 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, social partners, SMEs, fundamental rights experts and other relevant stakeholders 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.

#### Amendment 17

## Proposal for a regulation Recital 81

Text proposed by the Commission

The development of AI systems (81)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,

## Amendment

The development of AI systems (81)other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy, socially responsible and environmentally sustainable artificial intelligence in the Union. Providers of nonhigh-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,

PE731.563v02-00 386/665 RR\1279290EN.docx

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.

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 18

Proposal for a regulation Article 2 – paragraph 5 a (new)

Text proposed by the Commission

#### Amendment

5a. This Regulation shall not affect research activities regarding AI systems insofar as such activities do not lead to or entail placing an AI system on the market or putting it into service. These research activities shall not violate the fundamental rights of the affected persons.

## **Amendment 19**

Proposal for a regulation Article 2 – paragraph 5 b (new)

Text proposed by the Commission

### Amendment

5b. This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research in the general interest of the Union.

## **Amendment 20**

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, with varying levels of autonomy, for a given set of human-defined objectives, make predictions, content, recommendations, or decisions influencing real or virtual environments they interact with;

### **Amendment 21**

Proposal for a regulation Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

### Amendment

(1a) 'autonomy' means that an AI system operates by interpreting certain input 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 developer;

## **Amendment 22**

Proposal for a regulation Article 3 – paragraph 1 – point 2

Text proposed by the Commission

(1) '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;

### Amendment 23

## 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 *and* the failure or malfunctioning of which endangers the health and safety of persons or property;

## **Amendment 24**

## 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 *or malfunctioning of an AI* system that directly or indirectly leads, might have led or might lead to any of the following:

## **Amendment 25**

## 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 *fundamental rights*, health, *safety*, property or the environment,

## **Amendment 26**

Proposal for a regulation Article 3 – paragraph 1 – point 44 – point b a (new) Text proposed by the Commission

Amendment

(ba) breach of obligations under Union law intended to protect fundamental rights.

**Amendment 27** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44a) 'regulatory sandbox' means a facility established by one or more Member States' competent authorities in collaboration with the Commission or by the European Data Protection Supervisor, that provides an appropriate controlled and flexible environment to facilitate 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;

## **Amendment 28**

Proposal for a regulation Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44b) 'AI literacy' means the skills, knowledge and understanding regarding AI systems that are necessary for compliance with and enforcement of this Regulation;

**Amendment 29** 

Proposal for a regulation Article 3 – paragraph 1 – point 44 c (new)

PE731.563v02-00 390/665 RR\1279290EN.docx

## Text proposed by the Commission

## Amendment

(44c) 'deep fake' means manipulated or synthetic audio and/or visual material that gives an authentic impression, in which events appear to be taking place, which never happened, and which has been produced using techniques in the field of artificial intelligence, including machine learning and deep learning, without the user, or end-user being aware that the audio and/or visual material has been produced using artificial intelligence;

### Amendment 30

Proposal for a regulation Article 3 – paragraph 1 – point 44 d (new)

Text proposed by the Commission

Amendment

(44d) '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 (2020/0365(COD));

## Amendment 31

Proposal for a regulation Article 3 – paragraph 1 – point 44 e (new)

Text proposed by the Commission

Amendment

(44e) 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

## **Amendment 32**

## Proposal for a regulation Article 3 – paragraph 1 – point 44 f (new)

Text proposed by the Commission

Amendment

(44f) 'non personal data' means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679.

## **Amendment 33**

## 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 AI system as defined in Article 3, point (1), 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 34**

Proposal for a regulation Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

When drafting these delegated acts, the Commission shall ensure the input of all relevant stakeholders such as technical experts and developers of AI systems.

## **Amendment 35**

Proposal for a regulation Article 10 – paragraph 1

PE731.563v02-00 392/665 RR\1279290EN.docx

## 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, assessment, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 as far as this is feasible from a technical point of view while taking into account the latest state-of-the-art measures, according to the specific market segment or scope of application.

## **Amendment 36**

Proposal for a regulation Article 10 – paragraph 1 a (new)

Text proposed by the Commission

## Amendment

1a. 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.

### Amendment 37

Proposal for a regulation Article 10 – paragraph 1 b (new)

Text proposed by the Commission

### Amendment

1b. Providers of high-risk AI systems that utilise data collected and/or managed by third parties may rely on representations from those third parties with regard to quality criteria referred to in paragraph 2, points (a), (b) and (c)

## **Amendment 38**

## 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, assessment, 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, the following elements:

## **Amendment 39**

Proposal for a regulation Article 10 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) transparency as regards the original purpose of data collection;

## **Amendment 40**

Proposal for a regulation Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) data collection;

(b) data collection *processes*;

## **Amendment 41**

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, negatively impact fundamental rights or lead to discrimination prohibited by Union law; including the cases where data outputs

PE731.563v02-00 394/665 RR\1279290EN.docx

# are used as an input for future operations ('feedback loops');

### Amendment 42

## 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;

#### Amendment 43

Proposal for a regulation Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

#### Amendment

(ga) the purpose and the environment in which the system is to be used.

## **Amendment 44**

# 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 are designed with the best possible efforts to ensure that they are relevant, representative and appropriately vetted for errors in view of the intended purpose of the AI system. In particular, 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 45

# 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 take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural, *contextual* or functional setting within which the high-risk AI system is intended to be used.

### **Amendment 46**

## 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 following the principle of security by design and by default. In the light of their intended purpose, they should achieve an appropriate level of accuracy, robustness, safety, and cybersecurity, and perform consistently in those respects throughout their lifecycle. Compliance with these requirements shall include implementation of state-of-the-art measures, according to the specific market segment or scope of application.

## **Amendment 47**

Proposal for a regulation Article 15 – paragraph 1 a (new)

Text proposed by the Commission

## Amendment

1a. To address the technical aspects of to how to measure the appropriate levels

PE731.563v02-00 396/665 RR\1279290EN.docx

of accuracy and robustness set out in paragraph 1 of this Article, the European Artificial Intelligence Board shall bring together national metrology and benchmarking authorities and provide non-binding guidance on the matter as set out in Article 56, paragraph 2, point (a).

#### Amendment 48

Proposal for a regulation Article 15 – paragraph 1 b (new)

Text proposed by the Commission

#### Amendment

1b. To address any emerging issues across the internal market with regard to cybersecurity, the European Union Agency for Cybersecurity (ENISA) shall be involved alongside the European Artificial Intelligence Board as set out Article 56, paragraph 2, point (b).

#### **Amendment 49**

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 declared in the accompanying instructions of use. The language used shall be clear, free of misunderstandings or misleading statements.

#### Amendment 50

Proposal for a regulation Article 15 – paragraph 3 – subparagraph 1

### Text proposed by the Commission

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

Technical and organisational measures shall be taken to ensure that high-risk AI systems shall be as resilient as possible regarding 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 51

### Proposal for a regulation Article 15 – paragraph 3 – subparagraph 2

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 by the appropriate provider with input from the user, where necessary, through technical redundancy solutions, which may include backup or fail-safe plans.

### **Amendment 52**

# Proposal for a regulation Article 15 – paragraph 3 – subparagraph 3

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') *and malicious manipulation of inputs used in learning during operation* are duly addressed with appropriate mitigation measures.

#### **Amendment 53**

PE731.563v02-00 398/665 RR\1279290EN.docx

# Proposal for a regulation Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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.

#### Amendment

High-risk AI systems shall be resilient as regards *to* attempts by unauthorised third parties to alter their use, *behaviour*, *outputs* or performance by exploiting the system vulnerabilities.

#### Amendment 54

# Proposal for a regulation Article 15 – paragraph 4 – subparagraph 3

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 to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training dataset ('data poisoning'), or pre-trained components used in training ('model poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples' or 'model evasion'), confidentiality attacks or model flaws, which could lead to harmful decision-making.

### **Amendment 55**

Proposal for a regulation Article 40 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall ensure that the process of developing harmonised standards takes into account risks to fundamental rights, environment and society as a whole.

#### Amendment 56

Proposal for a regulation Article 40 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

The Commission shall ensure that the process of developing harmonised standards on AI systems is open to stakeholders, including SMEs in accordance with Articles 5 and 6 of Regulation (EU) No 1025/2012.

**Amendment 57** 

Proposal for a regulation Article 40 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

To this end the Commission shall direct funds in accordance with Article 17 of Regulation (EU) No 1025/2012 to facilitate their effective participation.

**Amendment 58** 

Proposal for a regulation Article 40 – paragraph 1 d (new)

Text proposed by the Commission

Amendment

The Commission shall review the harmonised standards before their publication in the Official Journal and prepare a report outlining their adequacy with paragraphs 1a and 1b of this Article.

**Amendment 59** 

Proposal for a regulation Article 41 – paragraph 1

PE731.563v02-00 400/665 RR\1279290EN.docx

### 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

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 and pressing safety or fundamental right concern that cannot be sufficiently settled by development of harmonised standards, 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 60**

# 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 developers and providers of High-risk AI systems as well as relevant stakeholders, such as SME's and start-ups, civil society and social partners or expert groups established under relevant sectorial Union law.

### **Amendment 61**

# 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

#### 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 shall be presumed to be in compliance with the requirement set out in Article 10(4). been trained and tested on data concerning the specific geographical, behavioural, **contextual** 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 62**

### Proposal for a regulation Article 42 – paragraph 2

Text proposed by the Commission

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>63</sup> and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

#### Amendment

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>63</sup> and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation, *where applicable*, in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

#### **Amendment 63**

Proposal for a regulation Article 43 – paragraph 1 – subparagraph 1 a (new)

PE731.563v02-00 402/665 RR\1279290EN.docx

<sup>&</sup>lt;sup>63</sup> Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

<sup>&</sup>lt;sup>63</sup> Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

### Text proposed by the Commission

#### Amendment

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.

#### **Amendment 64**

# 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. 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. The Commission shall consult the European Artificial Intelligence Board established in Article 56 as well as all relevant stakeholders.

#### **Amendment 65**

# 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

#### 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.

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. The Commission shall consult the European Artificial Intelligence Board established in Article 56 as well as all relevant stakeholders.

#### **Amendment 66**

# Proposal for a regulation Article 44 – paragraph 1

Text proposed by the Commission

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

#### Amendment

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

#### Amendment 67

# 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 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

PE731.563v02-00 404/665 RR\1279290EN.docx

conformity shall be given to the relevant national competent *authorities upon* request.

conformity shall be given to the relevant national competent authority in the Member State of main establishment of the provider, upon that competent authority's request.

#### **Amendment 68**

Proposal for a regulation Article 51 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

A high-risk AI system designed, developed, trained, validate, tested or approved to be placed on the market or put into service, outside the Union, can be registered in the EU database referred to in Article 60 and placed on the market or put into service in the Union only if it is proven that at all the stages of its design, development, training, validation, testing or approval, all the obligations required from such AI systems in the Union have been met.

#### Amendment 69

Proposal for a regulation Article 51 – paragraph 1 b (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 the Article 60. A new registration entry shall be complemented by the user for each high risk use of the AI system.

#### Amendment 70

### 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 in collaboration with the Commission, 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, SMEs, start-ups, enterprises, innovators or other relevant actors could be included as partners in the regulatory *sandboxes*. This shall take place under the direct supervision and guidance of the Commission in collaboration with the competent authorities with a view to identifying risks, in particular to health, safety, and fundamental rights, and 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.

#### Amendment 71

# Proposal for a regulation Article 53 – paragraph 2

Text proposed by the Commission

2. Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or

#### Amendment

2. Member States, *in collaboration with the Commission*, shall ensure that to the extent the innovative AI systems

PE731.563v02-00 406/665 RR\1279290EN.docx

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. 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 72

# 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, *including at regional or local level*. Any significant risks to health and safety, fundamental rights, *democracy or the environment*, 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.

### **Amendment 73**

### 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. Member States' competent authorities and the Commission shall coordinate their activities with regard to AI regulatory sandboxes and cooperate within the framework of the European Artificial Intelligence Board. The Commission shall submit annual reports to the European Artificial Intelligence Board on the results from the implementation of those schemes, including best practices,

RR\1279290EN.docx 407/665 PE731.563v02-00

recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.

computational energy use and efficiency, 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 be invited to share their good practices, lessons learnt and recommendations on their AI sandboxes with Member States' competent authorities.

#### Amendment 74

Proposal for a regulation Article 53 – paragraph 6 a (new)

*Text proposed by the Commission* 

#### Amendment

6a. 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.

#### **Amendment 75**

Proposal for a regulation Article 55 – title

Text proposed by the Commission

Amendment

Measures for *small-scale providers* and users

Measures for **SMEs**, **start-ups** and users

**Amendment 76** 

Proposal for a regulation Article 55 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) provide *small-scale providers* and

(a) provide *SMEs* and start-ups,

PE731.563v02-00 408/665 RR\1279290EN.docx

start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

established in the Union, with priority access to the AI regulatory sandboxes, to the extent that they fulfil the eligibility conditions:

#### Amendment 77

### 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 and enhanced digital skills development activities on the application of this Regulation tailored to the needs of SMEs, start-ups and users;

### **Amendment 78**

# 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) utilise existing dedicated channels and where appropriate, establish new dedicated channels for communication with SMEs, start-ups, users and other innovators to provide guidance and respond to queries about the implementation of this Regulation;

### Amendment 79

Proposal for a regulation Article 55 – paragraph 1 – point c a (new)

Text proposed by the Commission

#### Amendment

(ca) foster the participation of SMEs and other relevant stakeholders in the standardisation development process.

RR\1279290EN.docx 409/665 PE731.563v02-00

#### Amendment 80

# 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, start-ups and users shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to development stage, their size, market size and market demand. The Commission shall regularly assess the certification and compliance costs for SMEs and start-ups, including through transparent consultations with SMEs, start-ups and users and shall work with Member States to lower such costs where possible. The Commission shall report on these findings to the European Parliament and to the Council as part of the report on the evaluation and review of this Regulation provided for in Article 84(2).

### **Amendment 81**

Proposal for a regulation Article 57 – paragraph 3 a (new)

Text proposed by the Commission

#### Amendment

3a. The Board shall establish an AI Advisory Council (Advisory Council). The Advisory Council shall be composed of relevant representatives from industry, research, academia, civil society, standardisation organisations, 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

PE731.563v02-00 410/665 RR\1279290EN.docx

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.

#### **Amendment 82**

# Proposal for a regulation Annex I – point c

Text proposed by the Commission

(c) Statistical approaches, Bayesian estimation, search and optimization methods.

#### **Amendment 83**

Proposal for a regulation Annex IX a (new)

Text proposed by the Commission

#### Amendment

(c) Statistical approaches *to learning and inference*, Bayesian estimation, search and optimization methods.

#### Amendment

#### 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 Work 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 the expertise of relevant stakeholders from industry, SMEs, academia and civil society 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. The criteria for the access to the regulatory sandbox shall be transparent and competitive.
- 4. Participants in the sandboxing programme, in particular small-scale providers, are granted access to predeployment 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, consultation and support to conduct impact assessments of the AI systems to fundamental rights, environment or the society at large, an online social platform for the community, contact databases, existing portal for tenders and grant making and lists of EU investors.
- 5. The sandboxing programme shall, in a later development phase, aim at assisting Member States in developing and managing 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.
- 6. 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.
- 7. One of the objectives of the sandboxing programme is to enable firms'

PE731.563v02-00 412/665 RR\1279290EN.docx

- 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 as well as minimisation of risks to fundamental rights, environment and the society at large.
- 8. 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.
- 9. The sandboxing programme will have a built-in impact assessment procedure to facilitate the review of costeffectiveness 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.

# PROCEDURE - COMMITTEE ASKED FOR OPINION

Title	Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts	
References	COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)	
Committees responsible Date announced in plenary	IMCO LIBE 7.6.2021 7.6.2021	
Opinion by Date announced in plenary	ITRE 7.6.2021	
Associated committees - date announced in plenary	16.12.2021	
Rapporteur for the opinion Date appointed	Eva Maydell 11.1.2022	
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021	
Discussed in committee	21.3.2022	
Members present for the final vote	François-Xavier Bellamy, Hildegard Bentele, Tom Berendsen, Vasile Blaga, Michael Bloss, Marc Botenga, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Ignazio Corrao, Ciarán Cuffe, Nico Danti, Pilar del Castillo Vera, Martina Dlabajová, Christian Ehler, Ni Fuglsang, Lina Gálvez Muñoz, Jens Geier, Nicolás González Casares Christophe Grudler, Henrike Hahn, Robert Hajšel, Ivars Ijabs, Romar Jerković, Seán Kelly, Łukasz Kohut, Zdzisław Krasnodębski, Andrius Kubilius, Thierry Mariani, Marisa Matias, Eva Maydell, Iskra Mihaylova, Dan Nica, Angelika Niebler, Niklas Nienaß, Mauri Pekkarinen, Mikuláš Peksa, Tsvetelina Penkova, Morten Petersen, Pir Picierno, Clara Ponsatí Obiols, Manuela Ripa, Robert Roos, Sara Skyttedal, Maria Spyraki, Patrizia Toia, Pernille Weiss, Carlos Zorrin	
Substitutes present for the final vote	Franc Bogovič, Andrea Caroppo, Jakop G. Dalunde, Jens Gieseke, Klemen Grošelj, Elena Kountoura, Marian-Jean Marinescu, Dace Melbārde, Dominique Riquet, Rob Rooken, Susana Solís Pérez	
Substitutes under Rule 209(7) present for the final vote	Alessandra Basso, Bas Eickhout, Carlo Fidanza, Rob Rooken	

# FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

61	+
ECR	Carlo Fidanza, Zdzisław Krasnodębski, Dace Melbārde, Rob Rooken, Robert Roos
ID	Alessandra Basso, Thierry Mariani
NI	Clara Ponsatí Obiols
PPE	François-Xavier Bellamy, Hildegard Bentele, Tom Berendsen, Vasile Blaga, Franc Bogovič, Cristian-Silviu Buşoi, Jerzy Buzek, Andrea Caroppo, Maria da Graça Carvalho, Pilar del Castillo Vera, Christian Ehler, Jens Gieseke, Seán Kelly, Andrius Kubilius, Marian-Jean Marinescu, Eva Maydell, Angelika Niebler, Sara Skyttedal, Maria Spyraki, Pernille Weiss
RENEW	Nicola Danti, Martina Dlabajová, Klemen Grošelj, Christophe Grudler, Ivars Ijabs, Iskra Mihaylova, Mauri Pekkarinen, Morten Petersen, Dominique Riquet, Susana Solís Pérez
S&D	Niels Fuglsang, Lina Gálvez Muñoz, Jens Geier, Nicolás González Casares, Robert Hajšel, Ivo Hristov, Romana Jerković, Łukasz Kohut, Dan Nica, Tsvetelina Penkova, Pina Picierno, Patrizia Toia, Carlos Zorrinho
THE LEFT	Elena Kountoura
VERTS/ALE	Michael Bloss, Ignazio Corrao, Ciarán Cuffe, Jakop G. Dalunde, Bas Eickhout, Henrike Hahn, Niklas Nienaß, Mikuláš Peksa, Manuela Ripa

2	-
THE LEFT	Marc Botenga, Marisa Matias

0	0

Key to symbols: + : in favour - : against 0 : abstention

#### OPINION OF THE COMMITTEE ON CULTURE AND EDUCATION

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

on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

(COM(2021)0206 - C9-0146/2021 - 2021/0106(COD))

Rapporteur for opinion (\*): Marcel Kolaja

(\*) Associated committee – Rule 57 of the Rules of Procedure

#### SHORT JUSTIFICATION

On 24 April 2021, the European Commission published its legislative proposal laying down harmonised rules on artificial intelligence (AI Act), which introduces a regulatory framework with the objective of ensuring that AI systems placed on the European Union market are safe to use and respect fundamental rights and European Union values.

Furthermore, the proposal facilitates development of a single market for lawful, safe and trustworthy AI applications, enhances governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems and ensures legal certainty to facilitate investment and innovation in AI.

Overall, the Rapporteur welcomes the European Commission's proposal; however, would like to suggest a few amendments mainly to extend the list of high-risk AI applications in areas of education, media and culture under Annex III and to modify certain provisions related to banned practices under Article 5.

More specifically, the Rapporteur reflects on the increased deployment of AI technologies in education and training facilities. Therefore, he proposes listing, among high-risk technologies, also those AI technologies used for monitoring of students during tests and technologies used to determine an area or a programme a student should study. Regarding media and culture, the Rapporteur suggests listing high-risk AI technologies used to create or disseminate machinegenerated news articles used by news media outlets and AI technologies used to recommend or rank audiovisual content.

In addition, the Rapporteur proposes to extend the ban on deployment of social scoring systems to usage by public and private entities given the inherent threat of discrimination and exclusion of certain groups or individuals.

Finally, in light of the danger that deployment of remote biometric identification systems in

PE731.563v02-00 416/665 RR\1279290EN.docx



publicly accessible places poses to citizens' fundamental rights, freedom of assembly, work of investigative journalists, activists and political representatives, the Rapporteur proposes to ban deployment of such technologies in publicly accessible places following up on the Parliament resolution of 6 October 2021 on "Artificial intelligence in criminal law and its use by the police and judicial authorities in criminal matters".

#### **AMENDMENTS**

The Committee on Culture and Education calls on the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs, as the committees responsible, to take into account the following amendments:

#### Amendment 1

# Proposal for a regulation Recital 1

Text proposed by the Commission

The purpose of this Regulation is to (1) 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 AIbased 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

The purpose of this Regulation is to (1) improve the functioning of the internal market by laying down a uniform legal framework, based on ethical principles in particular for the development, marketing and use of artificial intelligence in conformity with Union values, minimising any risk of adverse and discriminatory impact on people and without hindering innovation. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights, democracy, the rule of law and the environment, 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 2

# 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 *trustworthy and* 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 in order to achieve trustworthy AI, while divergences hampering the free circulation, innovation, deployment and uptake 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.

PE731.563v02-00 418/665 RR\1279290EN.docx

#### Amendment 3

# Proposal for a regulation Recital 3

Text proposed by the Commission

(3) Artificial intelligence is a fast evolving family of technologies that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

#### Amendment

(3) Artificial intelligence is a fast evolving family of technologies that can contribute and is already contributing to a wide array of economic and societal benefits across the entire spectrum of industries and social activities, if developed in accordance with ethical principles. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, media, sports, culture infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

#### Amendment 4

# 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 including fundamental rights of workers, people in learning processes and socially engaged people, privacy, data protection and informational self-determination, societal or environmental rights. Such harm might

be material or immaterial.

#### Amendment 5

# 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 Council<sup>33</sup>, and it ensures the protection of ethical principles, as specifically requested by the European Parliament<sup>34</sup>.

A Union legal framework laying (5) 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, democracy, the rule of law and of the environment. 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 based on fundamental rights, as stated by the European Council<sup>33</sup>, and it ensures the protection of ethical principles, as specifically requested by the European Parliament<sup>34</sup>, with a human-centric approach and in compliance with freedom of expression, freedom of speech, media freedom, pluralism and diversity.

Amendment

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

<sup>&</sup>lt;sup>34</sup> European Parliament resolution of 20

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

<sup>&</sup>lt;sup>34</sup> 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).

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

#### Amendment 6

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

#### Amendment

(5a) In order to help promote the development, uptake and understanding of AI, the Union needs to put further effort into education and training, thus, inter alia, addressing the shortage of ICT professionals and AI undergraduate courses, digitally skilled workers as well as lack of even basic digital skills amongst a significant share of the population of the Union.

#### Amendment 7

Proposal for a regulation Recital 5 b (new)

Text proposed by the Commission

#### Amendment

(5b) Lack of both public and private investment is currently undermining development and use of AI systems across the Union, especially when compared to other major industrial economies. Special attention, incentives and support should be devised to promote AI uptake amongst SMEs, including those in education and cultural and creative sectors and industries.

#### **Amendment 8**

# 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 or virtual 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, and other private spaces. The same principle should apply to protected virtual publicly accessible 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, parks, sport complexes relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, shops, museums, libraries monuments, cultural sites, cultural *institutions* and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a caseby-case basis, having regard to the specificities of the individual situation at hand.

Amendment 9

Proposal for a regulation Recital 13

PE731.563v02-00 422/665 RR\1279290EN.docx

### 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

In order to ensure a consistent and (13)high level of protection of public interests as regards health, safety, fundamental rights, democracy, the rule of law, as well as the environment, a set of ethical principles and 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), the communication of the Commission of 11 December 2019 entitled 'The European Green Deal' and the European Declaration of 26 January 2022 on Digital Rights and Principles for the Digital Decade and should be nondiscriminatory and in line with the Union's international trade commitments.

#### Amendment 10

Proposal for a regulation Recital 14 b (new)

Text proposed by the Commission

#### Amendment

(14b) AI literacy refers to skills, knowledge and understanding that allows both citizens and operators in the context of the obligations set out in this Regulation to make an informed deployment and use of AI systems, as well as to gain awareness about the opportunities and risks of AI and thereby promote its democratic control. AI literacy should not be limited to learning about tools and technologies, but should also aim to equip citizens and operators in the context of the obligations set out in this Regulation with the critical thinking skills required to identify harmful or manipulative uses, as well as to improve their agency and their ability to fully comply with and benefit from trustworthy

AI. It is therefore necessary that the Commission, the Member States and operators of AI systems, in cooperation with all relevant stakeholders, promote the development of AI literacy, in all sectors of society, for citizens of all ages, including women and girls, and that progress in that regard is closely followed.

#### **Amendment 11**

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

#### Amendment

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

# Amendment 12Proposal 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

#### 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

PE731.563v02-00 424/665 RR\1279290EN.docx

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.

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 in the Union, as well as on society and on the environment, and such limitation minimises any potential restriction to international trade, if any.

#### Amendment 13

# 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

#### Amendment

AI systems could produce adverse (28)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

RR\1279290EN.docx 425/665 PE731.563v02-00

dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and nondiscrimination, 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.

dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and nondiscrimination, right to education, consumer protection, workers' rights. Special attention should be paid to gender equality, 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, protection of intellectual property rights and ensuring cultural diversity. 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 harm that an AI system can cause, including in relation to the health and safety of persons or to the environment, taking into account the extraction and consumption of natural resources, waste and the carbon footprint of those AI systems.

#### Amendment 14

# 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

Amendment

(33) Technical inaccuracies of AI systems intended for the biometric identification of natural persons can lead to biased results and entail discriminatory

PE731.563v02-00 426/665 RR\1279290EN.docx

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.

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 biometric identification systems should be subject to specific requirements on logging capabilities and human oversight. Nonremote biometric identification systems intended to be used in publicly accessible spaces, workplaces and education and training institutions can also present a high risk. The high risk of non-remote biometric identification systems intended to be used in publicly accessible spaces, workplaces and education and training institutions should be determined on a case-by-case basis.

### **Amendment 15**

Proposal for a regulation Recital 34 a (new)

Text proposed by the Commission

Amendment

(34a) Deployment of AI systems in education is crucial in order to help modernise entire education systems, to increase educational quality, both offline and online, and to accelerate digital education, thus also making it available to a broader audience. AI-aided digital education, whilst not a replacement for an in-person learning, is increasingly necessary to promote societal and economic growth, promote inclusiveness and increase educational attainment and accessibility to individuals.

#### **Amendment 16**

# 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

AI systems used in education or (35)training, notably for determining access or assigning persons to educational and training institutions to evaluate persons on tests as part of or as a precondition for their education or for determining the areas of study a student should follow 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, developed 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, 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 students' behaviour and emotion during tests at education and training institutions should be considered high-risk, since they are also interfering with students' rights to privacy and data protection. The use of AI to check assessments, such as exam papers for plagiarism, should not be considered high-risk.

#### Amendment 17

# 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

### Amendment

(36) AI systems used in employment, *employment support* 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, *for* 

PE731.563v02-00 428/665 RR\1279290EN.docx

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.

monitoring compliance with workplace rules and for monitoring or evaluation of persons in work-related relationships, should also be classified as high-risk, since those systems may appreciably impact the health, safety and security rules applicable in their work and at their workplaces and future career prospects and livelihoods of these persons. Relevant work-related 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 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. In this regard, specific requirements on transparency, information and human oversight should apply. Trade unions and workers' representatives should be informed and they should have access to any relevant documentation created under this Regulation for high-risk AI systems deployed or used in their work or at their workplace.

#### Amendment 18

# 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

#### Amendment

(70) Certain AI systems *used* to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they

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.

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 evidently used to form part of a creative, artistic or fictional cinematographic 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 include a disclaimer and should be provided inaccessible formats for children, the elderly, migrants and persons with disabilities or other vulnerabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content, texts or scripts that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose in a clear manner that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

#### Amendment 19

# 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

# 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 *AI literacy*,

PE731.563v02-00 430/665 RR\1279290EN.docx

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.

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 20

# Proposal for a regulation Recital 74

Text proposed by the Commission

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 AIon 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

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 AIon 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. It is necessary for the Commission to also create a pan-European network of universities and researchers focused on AI for enhanced studying and research on the impact of AI and to update the Digital Education Action Plan established in the

communication of the Commission of 30 September 2020 entitled 'Digital Education Action Plan 2021-2027 – Resetting education and training for the digital age', in order to integrate AI and robotics innovation in education.

#### **Amendment 21**

# 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 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 expert advice to and assisting the Commission on specific questions related to artificial intelligence and to addressing the challenges rising from the fast evolving development of AI technologies.

#### **Amendment 22**

# 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

#### 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 respect the

PE731.563v02-00 432/665 RR\1279290EN.docx

confidentiality of information and data obtained in carrying out their tasks.

confidentiality of information and data obtained in carrying out their tasks. It is appropriate for a new set of common European guidelines and standards to be set up in order to protect privacy while making an effective use of the data available.

#### **Amendment 23**

#### 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-Making<sup>58</sup>. 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

#### 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-Making<sup>58</sup>. Such consultations should involve qualified specialists from different areas of society including from the private sector, researchers and scientists, education,

RR\1279290EN.docx 433/665 PE731.563v02-00

Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

media and culture representatives, trade unions, consumer, parental and data protection organizations with skills and knowledge relevant to the task. 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 24

Proposal for a regulation Recital 86 a (new)

Text proposed by the Commission

#### Amendment

(86a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the delegation of powers and the implementing powers of the Commission should be exercised with as much flexibility as possible. The Commission should regularly review Annex III without undue delay, at least every six months, while consulting with the relevant stakeholders, including ethics experts, anthropologists, sociologists, mental health specialists and any other relevant scientists and researchers, as well as with parent associations.

**Amendment 25** 

Proposal for a regulation Article 1 – paragraph 1 – point c

PE731.563v02-00 434/665 RR\1279290EN.docx

<sup>&</sup>lt;sup>58</sup> OJ L 123, 12.5.2016, p. 1.

<sup>&</sup>lt;sup>58</sup> OJ L 123, 12.5.2016, p. 1.

# (c) 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

(c) harmonised transparency rules for AI systems;

#### **Amendment 26**

Proposal for a regulation Article 2 – paragraph 4 a (new)

Text proposed by the Commission

#### Amendment

4a. This Regulation shall not affect or undermine academic research or development of AI systems and their outputs for the purpose of academic research.

#### Amendment 27

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, *educational and training institution*, 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 28

Proposal for a regulation Article 3 – paragraph 1 – point 35

(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 behavioural data,* 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 29

#### 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, regardless of whether certain conditions for access may apply;

#### **Amendment 30**

#### 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 *fundamental rights*, health, to property or the environment, *to democracy or the democratic rule of law*,

#### **Amendment 31**

Proposal for a regulation Article 3 – paragraph 1 – point 44 a (new)

PE731.563v02-00 436/665 RR\1279290EN.docx

Amendment

(44a) 'education and training institutions' means providers of education and training, irrespective of the age of the persons receiving the education and training, including preschools, childcare, primary schools, secondary schools, tertiary education providers, vocational education and training and any type of lifelong learning providers;

#### **Amendment 32**

Proposal for a regulation Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44b) 'cultural institutions' means institutions such as libraries, museums, theatres, concert halls, exhibition centres, architectural ensembles and multipurpose arts venues, as well as their virtual sections, which organise cultural education, democratic exchanges and research and provide ways and means of engaging with cultural heritage;

#### Amendment 33

Proposal for a regulation Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44c) 'deep fake' means manipulated or synthetic audio, visual or audiovisual content, text or scripts which feature persons purported to be authentic and truthful;

#### Amendment 34

Proposal for a regulation Article 3 – paragraph 1 – point 44 d (new)

Text proposed by the Commission

Amendment

(44d) 'AI literacy' means the skills, knowledge and understanding regarding AI systems.

#### Amendment 35

Proposal for a regulation Article 4 a (new)

Text proposed by the Commission

Amendment

#### Article 4a

#### Trustworthy AI

- 1. All AI systems in the Union shall be developed, deployed and used in full respect of the Charter of Fundamental Rights of the European Union (the Charter).
- 2. In view of promoting trustworthy AI in the Union, and without prejudice to the requirements set out in Title III for high-risk AI systems, all AI systems shall be developed, deployed and used:
- (a) in a lawful, fair and transparent manner ('the principle of lawfulness, fairness and transparency');
- (b) in a manner that ensures that natural persons are always able to make informed decisions regarding such systems and that such systems do not undermine or override human autonomy ('the principle of human agency and oversight');
- (c) in a manner that ensures their safe, accurate and reliable performance, with embedded safeguards to prevent any kind of individual or collective harm ('the

PE731.563v02-00 438/665 RR\1279290EN.docx

principle of safety, accuracy, reliability and robustness');

- (d) in a manner that guarantees privacy and data protection ('the principle of privacy');
- (e) in a manner that privileges the integrity and quality of data, including with regard to access ('the principle of data governance');
- (f) in a traceable, auditable and explainable manner that ensures responsibility and accountability for their outcomes and supports redress ('the principle of traceability, auditability, explainability and accountability');
- (g) in a manner that does not discriminate against persons or groups of persons on the basis of unfair bias and that includes, to that end, the participation and input of relevant stakeholders('the principle of non-discrimination and diversity');
- (h) in an environmentally sustainable manner that minimises their environmental footprint, including with regard to the extraction and consumption of natural resources ('the principle of environmental sustainability');
- (i) in a socially responsible manner that minimises their negative societal impact, especially with regard to social and gender inequalities and democratic processes ('the principle of social responsibility').

**Amendment 36** 

Proposal for a regulation Article 4 b (new)

Text proposed by the Commission

Amendment

Article 4b

#### AI literacy

- 1. When implementing this Regulation, the Union and the Member States shall promote measures and tools for the development of a sufficient level of AI literacy, across sectors and groups of operators concerned, including through education and training, skilling and reskilling programmes and while ensuring a proper gender and age balance, in view of allowing a democratic control of AI systems.
- 2. Providers and users of AI systems shall promote tools and shall take measures to ensure a sufficient level of AI literacy of their staff and any other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the environment in which the AI systems are to be used, and considering the persons or groups of persons on which the AI systems are to be used.
- 3. Such literacy tools and measures shall consist, in particular, of the teaching and learning of basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits and the severity of the harm they can cause and its probability of occurrence.
- 4. The level of AI literacy shall be considered to be sufficient where it contributes to the ability of operators to fully comply with and benefit from trustworthy AI, and in particular with the requirements laid down in this Regulation.

**Amendment 37** 

Proposal for a regulation Article 6 – paragraph 2

PE731.563v02-00 440/665 RR\1279290EN.docx

## 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 due to their risk to cause harm to health, safety, the environment, fundamental rights or to democracy and the rule of law.

#### **Amendment 38**

#### Proposal for a regulation Article 7 – paragraph 1 – point a

Text proposed by the Commission

(a) the AI systems are intended to be used in any of the areas listed in *points 1 to* 8 of Annex III;

#### Amendment

(a) the AI systems are intended to be used in any of the areas listed in Annex III;

#### **Amendment 39**

#### 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 and safety, or a risk of adverse impact on fundamental rights, *democracy* and the rule of law, or the environment 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 40**

Proposal for a regulation Article 7 – paragraph 2 – introductory part

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, *democracy and the rule of law, or the environment* 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 41**

Proposal for a regulation Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Commission shall conduct the assessment referred to in paragraph 2 annually under the consultation conditions laid down in Article 73.

#### **Amendment 42**

Proposal for a regulation Article 9 – paragraph 4 – subparagraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(da) provision of a sufficient level of AI literacy;

#### Amendment 43

Proposal for a regulation Article 9 – paragraph 8

Text proposed by the Commission

Amendment

8. When implementing the risk

8. When implementing the risk

PE731.563v02-00 442/665 RR\1279290EN.docx

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. 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, the elderly, migrants or other vulnerable groups.

#### Amendment 44

#### 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, in particular deviations that could affect the health and safety of people or could lead to discrimination;

#### **Amendment 45**

Proposal for a regulation Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

#### Amendment

(ga) the purpose and the environment in which the system is to be used;

#### **Amendment 46**

#### 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

#### 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 *providers and* users *and other relevant stakeholders to easily* interpret the system's *functioning and* output and use it appropriately *on the basis* 

RR\1279290EN.docx 443/665 PE731.563v02-00

view to achieving compliance with the relevant obligations *of the user and of the provider* set out in Chapter 3 of this Title.

of informed decisions, with a view to achieving compliance with the relevant obligations set out in Chapter 3 of this Title

#### Amendment 47

Proposal for a regulation Article 13 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in accordance with Article 4b.

#### **Amendment 48**

Proposal for a regulation Article 14 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in accordance with Article 4b.

#### Amendment 49

Proposal for a regulation Article 29 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. In order to comply with the obligations laid down in this Article, as well as to be able to justify their possible non-compliance, users of high-risk AI systems shall ensure a sufficient level of

PE731.563v02-00 444/665 RR\1279290EN.docx

#### Amendment 50

#### 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 stakeholders, including industry representatives, SMEs and other* relevant bodies or expert groups established under relevant sectorial Union law.

#### Amendment 51

#### 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 *used* 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 52

Proposal for a regulation Article 52 – paragraph 2

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, in a timely, clear and intelligible manner, of the operation of the system the natural persons exposed thereto. That information shall also include, as appropriate, the rights and processes to allow natural persons to appeal against the application of such AI systems to them. 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 53

#### Proposal for a regulation Article 52 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Users of an AI system that generates or manipulates image, audio, *text*, *scripts* or video content that appreciably resembles existing persons, objects, places, *text*, *scripts* 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*, *repetitive*, *timely and visible manner*, that the content has been artificially generated or manipulated.

#### **Amendment 54**

Proposal for a regulation Article 52 – paragraph 3 – subparagraph 2

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* 

Amendment

However, the first subparagraph shall not apply where the use *forms part of an evidently artistic, creative or fictional* 

PE731.563v02-00 446/665 RR\1279290EN.docx

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.

cinematographic or analogous work or where it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.

#### **Amendment 55**

Proposal for a regulation Article 52 – paragraph 3 a (new)

Text proposed by the Commission

#### Amendment

3a. Providers and users of AI systems that recommend, disseminate and order news or creative and cultural content shall disclose, in an appropriate, easily accessible, clear and visible manner, the main parameters used for the moderation of content and personalized suggestions. That information shall include a disclaimer.

#### Amendment 56

Proposal for a regulation Article 52 – paragraph 3 b (new)

Text proposed by the Commission

#### Amendment

3b. The information referred to in this Article shall be provided to the natural persons in a timely, clear and visible manner, at the latest at the time of the first interaction or exposure. Such information shall be made accessible when the exposed natural person is a person with disabilities, a child or where he or she belongs to a vulnerable group. It shall be complete, where possible, with intervention or flagging procedures for the exposed natural person, taking into account the generally acknowledged state

## of the art and relevant harmonised standards and common specifications.

#### Amendment 57

Proposal for a regulation Article 56 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) work towards promoting uptake of AI within the Union, especially amongst SMEs;

#### **Amendment 58**

#### 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. Other national *or international* authorities *and relevant stakeholders, including from the private sector, shall* be invited to the meetings, where the issues discussed are of relevance for them.

#### **Amendment 59**

#### 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

#### Amendment

4. The Board *shall, where relevant,* invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to

PE731.563v02-00 448/665 RR\1279290EN.docx

appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups. 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, *including the High-Level Expert Group on AI*.

#### Amendment 60

#### 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 both, including with the involvement of users and any interested stakeholders and their representative organisations, *including in particular trade unions and consumers 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 61**

Proposal for a regulation Article 69 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in accordance with Article 4b.

#### **Amendment 62**

#### Proposal for a regulation

RR\1279290EN.docx 449/665 PE731.563v02-00

#### 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 market position of small-scale providers and start-up and their economic viability.

#### **Amendment 63**

Proposal for a regulation Article 73 – paragraph 3 a (new)

Text proposed by the Commission

#### Amendment

3a. 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.

#### **Amendment 64**

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, *telecommunications*,

PE731.563v02-00 450/665 RR\1279290EN.docx

#### and electricity.

#### **Amendment 65**

#### Proposal for a regulation Annex III – paragraph 1 – point 3 – introductory part

Text proposed by the Commission

Amendment

3. Education and *vocational* training: 3.

3. Education and training:

#### **Amendment 66**

#### 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 intended to be used for the purpose of determining access or assigning natural persons to educational and training institutions;

#### Amendment 67

#### 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 training institutions and for assessing participants in tests commonly required for admission to educational institutions.

#### **Amendment 68**

Proposal for a regulation Annex III – paragraph 1 – point 3 – point b a (new)

Amendment

(ba) AI systems intended to be used for the purpose of determining the study programme or areas of study to be followed by students in education and training institutions;

#### Amendment 69

Proposal for a regulation Annex III – paragraph 1 – point 3 – point b b (new)

Text proposed by the Commission

Amendment

(bb) AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests at education and training institutions;

#### Amendment 70

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 employment support*, workers management and access to self-employment:

#### Amendment 71

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

Amendment

(b) AI intended to be used for making decisions on *establishment*, promotion and termination of work-related relationships, for task allocation, *for monitoring compliance with workplace rules* and for

PE731.563v02-00 452/665 RR\1279290EN.docx

persons in such relationships.

monitoring and evaluating performance and behavior of persons in such relationships.

## ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the opinion, until the adoption thereof in committee:

Entity and/or person
AccessNow
Baptiste Caramiaux, CNRS researcher, Sorbonne Université in Paris
BEUC
Defenddigitalme
EDRi
European Disability Forum
Huawei
International Federation of Library Associations and Institutions
Joanna Bryson, Professor of Ethics and Technology, Hertie School
Liber Europe
Maldita.es
Martin Senftlebe, Professor of Intellectual Property Law, University of Amsterdam
Meaning Processing Ltd.
Saidot Ltd.
Scio.cz

#### PROCEDURE - COMMITTEE ASKED FOR OPINION

Title	Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts	
References	COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)	
Committees responsible Date announced in plenary	IMCO LIBE 7.6.2021 7.6.2021	
Opinion by Date announced in plenary	CULT 7.6.2021	
Associated committees - date announced in plenary	16.12.2021	
Rapporteur for the opinion Date appointed	Marcel Kolaja 13.7.2021	
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021	
Discussed in committee	15.3.2022	
Date adopted	15.6.2022	
Result of final vote	+: 24 -: 0 0: 0	
Members present for the final vote	Asim Ademov, Ilana Cicurel, Tomasz Frankowski, Romeo Franz, Catherine Griset, Sylvie Guillaume, Hannes Heide, Petra Kammerevert, Niyazi Kizilyürek, Predrag Fred Matić, Dace Melbārde, Peter Pollák, Diana Riba i Giner, Andrey Slabakov, Massimiliano Smeriglio, Michaela Šojdrová, Sabine Verheyen, Theodoros Zagorakis, Milan Zver	
Substitutes present for the final vote	Loucas Fourlas, Ibán García Del Blanco, Marcel Kolaja, Domènec Ruiz Devesa	
Substitutes under Rule 209(7) present for the final vote	Karen Melchior	

#### FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

24	+
ECR	Dace Melbārde, Andrey Slabakov
ID	Catherine Griset
PPE	Asim Ademov, Loucas Fourlas, Tomasz Frankowski, Peter Pollák, Michaela Šojdrová, Sabine Verheyen, Theodoros Zagorakis, Milan Zver
RENEW	Ilana Cicurel, Karen Melchior
S&D	Ibán García Del Blanco, Sylvie Guillaume, Hannes Heide, Petra Kammerevert, Predrag Fred Matić, Domènec Ruiz Devesa, Massimiliano Smeriglio
THE LEFT	Niyazi Kizilyürek
VERTS/ALE	Romeo Franz, Marcel Kolaja, Diana Riba i Giner
0	_

0	-

0	0

Key to symbols: + : in favour - : against 0 : abstention

PE731.563v02-00 456/665 RR\1279290EN.docx

#### **OPINION OF THE COMMITTEE ON LEGAL AFFAIRS**

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

on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

(COM(2021)0206 - C9-0146/2021 - 2021/0106(COD))

Rapporteur for opinion: Axel Voss

#### **AMENDMENTS**

The Committee on Legal Affairs calls on the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs, as the committees responsible, to take into account the following amendments:

#### Amendment 1

## 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,

#### 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 *principles and democratic* 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

marketing and use of AI systems, unless explicitly authorised by this Regulation.

restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

#### Amendment 2

## Proposal for a regulation Recital 3

Text proposed by the Commission

Artificial intelligence is a fast evolving family of technologies that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

#### Amendment

Artificial intelligence is a fast (3) evolving family of technologies that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities if developed in accordance with relevant general principles in line with the EU Charter of Fundamental Rights and the values on which the Union is founded. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

#### **Amendment 3**

## 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

PE731.563v02-00 458/665 RR\1279290EN.docx

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. Such harm might be material or immaterial and might affect a person, a group of persons or society as a whole.

#### **Amendment 4**

## Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

#### Amendment

(6a) Building on the seven key requirements set out by the High-Level Expert Group on Artificial Intelligence, it is important to note that AI systems should respect general principles establishing a high-level framework that promotes a coherent human-centric approach to ethical and trustworthy AI in line with the Charter of Fundamental Rights of the European Union and the values on which the Union is founded, including the protection of fundamental rights, human agency and oversight, technical robustness and safety, privacy and data governance, transparency, nondiscrimination and fairness and societal and environmental wellbeing.

#### Amendment 5

## 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

#### Amendment

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety, fundamental rights *and the environment*, 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

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

European Union (the Charter), the European Green Deal (The Green Deal) and the Joint Declaration on Digital Rights of the Union (the Declaration) and should be non-discriminatory and in line with the Union's international commitments.

#### Amendment 6

Proposal for a regulation Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) For this Regulation to be effective, it is essential to address the issue of the digital divide and, therefore, it should be accompanied by a policy of education, training and awareness as regards these technologies that ensures a sufficient level of AI literacy.

#### Amendment 7

Proposal for a regulation Recital 14 b (new)

Text proposed by the Commission

Amendment

(14b) 'AI literacy' refers to skills, knowledge and understanding that allows providers, users and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause and thereby promote its democratic control. AI literacy should not be limited to learning about tools and technologies, but should also aim to equip providers and users with the notions and skills required to ensure compliance with and enforcement of this Regulation. It is

PE731.563v02-00 460/665 RR\1279290EN.docx

therefore necessary that the Commission, the Member States as well as providers and users of AI systems, in cooperation with all relevant stakeholders, promote the development of a sufficient level of AI literacy, in all sectors of society, for citizens of all ages, including women and girls, and that progress in that regard is closely followed.

#### Amendment 8

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

### Amendment

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

#### Amendment 9

## 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

#### 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 humanmachine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

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 nonsupervised 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 and in accordance with this Regulation, further flexibilities in order to foster research, and thereby European innovation capacities, should be introduced by Member States.

#### Amendment 10

## Proposal for a regulation Recital 28

Text proposed by the Commission

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

#### Amendment

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

PE731.563v02-00 462/665 RR\1279290EN.docx

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 nondiscrimination, 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.

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 nondiscrimination, education, consumer protection, workers' rights, gender equality, 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, right to protection of intellectual property, cultural diversity. 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.

#### **Amendment 11**

Proposal for a regulation Recital 47 a (new)

#### Amendment

(47a) Such requirements on transparency and on the explicability of AI decision-making should also help to counter the deterrent effects of digital asymmetry and so-called 'dark patterns' targeting individuals and their informed consent.

#### **Amendment 12**

Proposal for a regulation Recital 48 a (new)

Text proposed by the Commission

#### Amendment

(48a) Human oversight aims at serving human-centric objectives. The individuals to whom human oversight is assigned should be provided with adequate education and training on the functioning of the AI system, its capabilities to influence or make decisions, the possible harmful effects it can cause, notably on fundamental rights, and its probability of occurrence. The persons in charge of the assignment of these individuals should provide them with the necessary staff and psychological support and authority to exercise their function.

#### **Amendment 13**

Proposal for a regulation Recital 57 a (new)

Text proposed by the Commission

Amendment

(57a) AI systems, which have been placed on the market but require further training or the use of a model not provided by the provider should be considered as general purpose AI system. The training of these systems after they

have been placed in the market should be considered as adapting them to a specific purpose;

**Amendment 14** 

Proposal for a regulation Recital 57 b (new)

Text proposed by the Commission

Amendment

(57b) Open Source software licences allow users to run, copy, distribute, study, change and improve software freely. By default the use of Open Source software in this manner attributes liability to the user, whereas when a provider provides Open Source software commercially under a Software as a Service (SaaS) or Professional Services model, then the provider may retain the liability instead of the user. Research by the European Commission shows that Open Source software contributes between €65bn -€95bn to the European Union's GDP, and provides significant growth opportunities for the Union economy. Open Source providers should be able to adopt the same economic model for AI systems. Hence, the provisions of this Regulation should not apply to Open Source AI systems until those systems are put into service. To ensure that AI systems cannot be put into service without complying with this Regulation, when an Open Source AI System is put into service, the obligations associated with providers should be transferred to the person putting the system into service.

**Amendment 15** 

Proposal for a regulation Recital 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

In order to promote and protect (73)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 AI literacy, 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 16

## 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

#### Amendment

(76) In order to avoid fragmentation and ensure the optimal functioning of the Single Market, it is essential to guarantee an effective and harmonised implementation of this Regulation. To this end, a European Artificial Intelligence Board should be established and entrusted with 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

PE731.563v02-00 466/665 RR\1279290EN.docx

Commission on specific questions related to artificial intelligence.

requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence. However, such a solution might prove not to be sufficient to ensure a fully coherent cross-border action and, therefore, [within three years after the date of application of this Regulation], the Commission should be required to consider whether the creation of an EU Agency is necessary to ensure a consistent application of this Regulation at Union level.

#### **Amendment 17**

Proposal for a regulation Recital 76 a (new)

Text proposed by the Commission

Amendment

(76a) The Commission should reestablish 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,
social partners and civil society. This new
High Level Expert Group on Trustworthy
AI 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 on Trustworthy AI must
have the chance to share its practical and
technical expertise in a special meeting
with the Board.

#### **Amendment 18**

## 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

Amendment

(77) Member States hold a key role in the application and enforcement of this

RR\1279290EN.docx 467/665 PE731.563v02-00

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.

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. In order to facilitate a consistent and coherent implementation of this Regulation, national supervisory authorities should engage in substantial and regular cooperation not only with the Board, but also among themselves to promote the exchange of relevant information and best practices. In this regard and also taking into account that, given the current lack of AI experts, it might be difficult to ensure at national level that the supervisory authorities are provided with adequate human resources to perform their tasks. Member States are also strongly encouraged to consider the possibility of creating transnational entities for the purpose of ensuring joint supervision of the implementation of this Regulation.

#### Amendment 19

Proposal for a regulation Recital 80 a (new)

Text proposed by the Commission

Amendment

(80a) Natural or legal persons affected by decisions made by AI systems which produce legal effects that adversely affect their health, safety, fundamental rights, socio-economic well-being or any other of their rights deriving from the obligations laid down in this Regulation, should be entitled to an explanation of that decision. Such an explanation is to be provided to

PE731.563v02-00 468/665 RR\1279290EN.docx

the affected persons and, therefore, when providing such an explanation, providers and users should duly take into account that the level of expertise and knowledge of the average consumer or citizen regarding AI systems is limited and much lower than the one that they possess. On the other hand, some AI systems cannot provide an explanation for their decisions beyond the initial input data. When AI systems are required to provide an explanation and cannot, they should clearly state that an explanation cannot be provided. This should be taken into account by any administrative, nonadministrative or judicial authority dealing with complaints from affected persons.

## **Amendment 20**

# 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

## 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-Making 58. 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.

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-Making<sup>58</sup>. *These* consultations should involve the participation of a balanced selection of stakeholders, including consumer organisations, associations representing affected persons, business representatives from different sectors and of different sizes, trade unions 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.

### **Amendment 21**

Proposal for a regulation Recital 86 a (new)

Text proposed by the Commission

Amendment

(86a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the powers delegated to the Commission and the implementing powers conferred on it should be exercised with as much flexibility as possible. The Commission should regularly review Annex III without undue delay while consulting with the relevant stakeholders.

### **Amendment 22**

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

PE731.563v02-00 470/665 RR\1279290EN.docx

## 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 *human-centric and trustworthy* artificial intelligence systems ('AI systems') in the Union *in compliance with democratic values*;

### **Amendment 23**

# 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;

## **Amendment 24**

# 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 *governance*, market monitoring, *market* surveillance *and enforcement*;

## **Amendment 25**

Proposal for a regulation Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(ea) a high level protection of public

interests, such as health, safety, fundamental rights and the environment, against potential harms caused by artificial intelligence;

## **Amendment 26**

Proposal for a regulation Article 1 – paragraph 1 – point e b (new)

Text proposed by the Commission

Amendment

(eb) 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;

### **Amendment 27**

Proposal for a regulation Article 1 – paragraph 1 – point e c (new)

Text proposed by the Commission

Amendment

(ec) provisions on the establishment of an independent 'European Artificial Intelligence Board' and on its activities supporting the enforcement of this Regulation.

### **Amendment 28**

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* located *or established* within the Union;

### **Amendment 29**

PE731.563v02-00 472/665 RR\1279290EN.docx

# 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, meaning predictions, recommendations or decisions produced by the system and influencing the environment it interacts with, is used in the Union and puts at risk the environment or the health, safety or fundamental rights of natural persons physically present in the Union, insofar as the provider or user has permitted, is aware or can reasonably expect such a use;

### Amendment 30

Proposal for a regulation Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) importers, distributors, and authorised representatives of providers of AI systems;

### Amendment 31

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:
- (a) Regulation (EC) 300/2008;

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 the *listed acts in Annex II*, *section B*, only Article 84 of this Regulation shall apply.

RR\1279290EN.docx 473/665 PE731.563v02-00

- (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.

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

**Amendment 33** 

Proposal for a regulation Article 2 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

*3a*. This Regulation shall not affect research, testing and development activities regarding an AI system prior to this system being placed on the market or put into service, provided that these activities are conducted respecting fundamental rights and the applicable Union law. The Commission is empowered to adopt delegated acts in accordance with Article 73 to specify this exemption. The Board shall provide guidance on the governance of research and development pursuant to Article 56 (2) (cc), also aiming at coordinating the way this exemption is put in place by the Commission and the national supervisory authorities.

PE731.563v02-00 474/665 RR\1279290EN.docx

Proposal for a regulation Article 2 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. Title III of this Regulation shall not apply to AI systems that are used in a strictly business-to-business environment and provided that those systems do not pose a risk of harm to the environment, health or safety or a risk of adverse impact on fundamental rights.

## **Amendment 35**

Proposal for a regulation Article 2 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. This regulation shall not apply to Open Source AI systems until those systems are put into service or made available on the market in return for payment, regardless of if that payment is for the AI system itself, the provision of the AI system as a service, or the provision of technical support for the AI system as a service.

## **Amendment 36**

Proposal for a regulation Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

Amendment

(1a) 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 intended by the provider 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;

### Amendment 37

Proposal for a regulation Article 3 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1b) 'open source AI systems' means AI systems, including test and training data, or trained models, distributed under open licenses.

#### **Amendment 38**

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 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 or that adapts general purpose AI systems to a specific intended purpose;

### **Amendment 39**

Proposal for a regulation Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4a) 'affected person' means any natural person or a group of persons who

PE731.563v02-00 476/665 RR\1279290EN.docx

## are subject to or affected by an AI system

### **Amendment 40**

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

### **Amendment 41**

Proposal for a regulation Article 3 – paragraph 1 – point 44 a (new)

Text proposed by the Commission

Amendment

(44a) 'AI literacy' means the skills, knowledge and understanding regarding AI systems that are necessary for the compliance with and enforcement of this Regulation.

### Amendment 42

Proposal for a regulation Article 4 a (new)

Text proposed by the Commission

Amendment

### Article 4a

General principles applicable to all AI systems

1. All AI operators shall respect the following general principles that establish a high-level framework that promotes a coherent human-centric European approach to ethical and trustworthy Artificial Intelligence, which is fully in line with the Charter as well as the values

on which the Union is founded:

- '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 appropriately controlled and overseen by humans.
- '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 unintended problems and being resilient against attempts to alter the use or performance of the AI system so as to allow unlawful use 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 and affected persons about their rights.
- '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, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national 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-

PE731.563v02-00 478/665 RR\1279290EN.docx

term impacts on the individual, society and democracy.

2. Paragraph 1 is without prejudice to obligations set up by existing Union and national law.

For high-risk AI systems, the general principles are translated into and complied with by providers or users by means of the requirements set out in Articles 8 to 15 of this Regulation. 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 is strongly encouraged with a view to fulfilling the principles listed in paragraph 1.

3. The Commission and the Board shall issue recommendations that help guiding providers and users on how to develop and use AI systems in accordance with the general principles. European Standardisation Organisations shall take the general principles referred to in paragraph 1 into account as outcomebased objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b).

Amendment 43

Proposal for a regulation Article 4 b (new)

Text proposed by the Commission

Amendment

Article 4b

AI literacy

1. When implementing this Regulation, the Union and the Member States shall promote measures and tools for the development of a sufficient level of AI literacy, across sectors and taking into account the different needs of groups of

- providers, users and affected persons concerned, including through education and training, skilling and reskilling programmes and while ensuring proper gender and age balance, in view of allowing a democratic control of AI systems.
- 2. Providers and user of AI systems shall promote tools and take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the environment the AI systems are to be used in, and considering the persons or groups of persons on which the AI systems are to be used.
- 3. Such literacy tools and measures shall consist, in particular, of the teaching and learning of basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits and the severity of the possible harm they can cause and its probability of occurrence.
- 4. A sufficient level of AI literacy is one that contributes, as necessary, to the ability of providers and users to ensure compliance and enforcement of this Regulation.

Proposal for a regulation Article 9 – paragraph 4 - subparagraph 2 – 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 training to users, *as appropriate to ensure a sufficient* 

PE731.563v02-00 480/665 RR\1279290EN.docx

# 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 of AI systems already covered by other acts of Union law that require them to put in place specific risk management systems, including 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 acts of Union law.

### **Amendment 46**

# Proposal for a regulation Article 13 – title

Text proposed by the Commission

Transparency and provision of information *to users* 

## Amendment

Transparency and provision of information

## **Amendment 47**

## 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

### 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 *providers and* users to *reasonably understand* the system's *functioning*. Appropriate transparency shall be ensured *in accordance with the intended purpose of the AI system*, with a view to achieving compliance with the

set out in Chapter 3 of this Title.

relevant obligations of the provider *and user* set out in Chapter 3 of this Title.

Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall be enabled to understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, allowing the user to explain the decisions taken by the AI system to the affected person pursuant to Article 68(c).

### Amendment 48

# 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 *intelligible* instructions for use in an appropriate digital format or *made* otherwise *available in a durable medium* that include concise, *correct, clear and to the extent possible* complete information that *helps operating and maintaining the AI system as well as supporting informed decision-making by users and is reasonably* relevant, accessible and comprehensible to users.

## **Amendment 49**

# 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 achieve the outcomes referred to in paragraph 1, information referred to

PE731.563v02-00 482/665 RR\1279290EN.docx

## in paragraph 2 shall specify:

### Amendment 50

# 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 and, where applicable, of its authorised *representatives*;

### Amendment 51

Proposal for a regulation Article 13 – paragraph 3 – point a a (new)

Text proposed by the Commission

Amendment

(aa) where it is not the same as the provider, the identity and the contact details of the entity that carried out the conformity assessment and, where applicable, of its authorised representative;

### Amendment 52

# Proposal for a regulation Article 13 – paragraph 3 – point b – introductory part

Text proposed by the Commission

Amendment

- (b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:
- (b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including, *where appropriate*:

# **Amendment 53**

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 *clearly* known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

### **Amendment 54**

## 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 clearly 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, fundamental rights or the environment, including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used;

### **Amendment 55**

Proposal for a regulation Article 13 – paragraph 3 – point b – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) the degree to which the AI system can provide an explanation for decisions it takes;

# **Amendment 56**

PE731.563v02-00 484/665 RR\1279290EN.docx

# 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.

### **Amendment 57**

Proposal for a regulation Article 13 – paragraph 3 – point e

Text proposed by the Commission

(e) the expected lifetime of the highrisk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.

### Amendment

(e) any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates, *through its expected lifetime*.

### Amendment 58

Proposal for a regulation Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

## Amendment

(ea) a description of the mechanisms included within the AI system that allows users to properly collect, store and interpret the logs in accordance with Article 12(1).

### Amendment 59

Proposal for a regulation Article 13 – paragraph 3 – point e b (new)

RR\1279290EN.docx 485/665 PE731.563v02-00

## Text proposed by the Commission

### Amendment

(eb) The information shall be provided at least in the language of the country where the AI system is used.

### **Amendment 60**

Proposal for a regulation Article 13 – paragraph 3 a (new)

Text proposed by the Commission

### Amendment

3a. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in line with Article 4b.

### **Amendment 61**

# 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

High-risk AI systems shall be 1. designed and developed in such a way, including with appropriate human-machine interface tools, that they be effectively overseen by natural persons as proportionate to the risks associated with those systems. Natural persons in charge of ensuring human oversight shall have sufficient level of AI literacy in accordance with Article 4b and the necessary support and authority to exercise that function, during the period in which the AI system is in use and to allow for thorough investigation after an incident.

## **Amendment 62**

PE731.563v02-00 486/665 RR\1279290EN.docx

# 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, fundamental rights or environment 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 and where decisions based solely on automated processing by AI systems produce legal or otherwise significant effects on the persons or groups of persons on which the system is to be used.

### Amendment 63

# 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 take into account 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:

### Amendment 64

# 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 natural persons to whom human oversight is assigned are enabled, as

RR\1279290EN.docx 487/665 PE731.563v02-00

appropriate *and proportionate* to the circumstances:

### Amendment 65

# 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) be aware of 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;

### **Amendment 66**

# 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, the system through a "stop" button or a similar procedure that allows the system to come to a halt in a safe state, except if the human interference increases the risks or would negatively impact the performance in consideration of generally acknowledged state-of-theart.

### Amendment 67

# 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

## Amendment

5. For high-risk AI systems referred to in point1(a) of Annex III, the measures

PE731.563v02-00 488/665 RR\1279290EN.docx

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.

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 with the necessary competence, training and authority.

### **Amendment 68**

# 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;

### Amendment 69

Proposal for a regulation Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

### Amendment

(aa) 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;

### Amendment 70

Proposal for a regulation Article 16 – paragraph 1 – point c

Text proposed by the Commission

(c) *draw-up* the technical

Amendment

(c) keep the documentation and,

RR\1279290EN.docx 489/665 PE731.563v02-00

documentation of the high-risk AI system;

where not yet available, draw up the technical documentation referred to in Article 18:

### Amendment 71

## 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 highrisk AI systems;

### Amendment

(d) when under their control, keep the logs automatically generated by their highrisk AI systems, *in accordance with Article 20*;

### Amendment 72

# 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;

# **Amendment 73**

# 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;

## **Amendment 74**

PE731.563v02-00 490/665 RR\1279290EN.docx

# 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 75

Proposal for a regulation Article 23 a (new)

Text proposed by the Commission

#### 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.

#### Amendment

### Article 23a

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 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 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 place on the market or make

- available on the market, with or without modification and in return for payment an Open Source AI system, an AI system derived from an Open Source AI system, or Technical Support Services for any such Open Source AI systems;
- (e) they adapt a general purpose AI system, already placed on the market or put into service, to a specific intended purpose.
- 2. Where the circumstances referred to in paragraph 1, points (a), (b), (c) or (d), occur, the former 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 former provider shall upon request and respecting 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 as referred to in paragraph 1, point (e), shall, respecting its own intellectual property rights or trade secrets and taking into account the risks that are specifically linked to the adaption of the general purpose AI system to a specific intended purpose:
- (a) ensure that the general purpose AI system which may be used as high-risk AI system complies with the requirements established in Articles 9, 10, 11, 13(2) and (3), 14(1) and 15 of this Regulation;
- (b) comply with the obligations set out in Articles 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;

PE731.563v02-00 492/665 RR\1279290EN.docx

- (d) provide the new provider referred to in paragraph 1, point (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, or providers of network services shall not be considered providers for the purposes of this Regulation.

# 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 take appropriate organisational measures and ensure that the use of such systems takes place in accordance with the instructions of use accompanying the systems pursuant to paragraphs 1a to 5 of this Article. Users shall bear responsibility in case of any use of the AI system that is not in accordance with the instructions of

## use accompanying the systems.

### Amendment 77

# Proposal for a regulation Article 29 – paragraph 1 a (new)

Text proposed by the Commission

### Amendment

1a. To the extent the user exercises control over the high-risk AI system, that user shall assign human oversight to natural persons who have the necessary AI literacy in accordance with Article 4b.

## **Amendment 78**

# 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 *paragraphs 1* and 1a are without prejudice to other obligations of the user 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 79

# 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.

PE731.563v02-00 494/665 RR\1279290EN.docx

# Proposal for a regulation Article 29 – paragraph 4 – subparagraph 1

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

Users shall monitor the operation of 4. the high-risk AI system on the basis of the instructions of use and, when relevant, inform the provider in accordance with Article 61. To the extent the user exercises control over the high-risk AI system, it shall also perform a risk assessment in accordance with Article 9 but limited to the potential adverse effects of using the high-risk AI system as well as 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 and competent supervisory authority when they have identified any serious incident or malfunctioning and interrupt the use of the AI system. In case the user is not able to reach the provider *importer* or distributer. Article 62 shall apply mutatis mutandis.

## **Amendment 81**

# Proposal for a regulation Article 29 – paragraph 5 – subparagraph 1

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 *and is feasible from a technical point of view. They* shall *keep them* for a period *of at least six months, unless provided otherwise in* applicable Union or national law.

# 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*, where applicable, *to those data protection impact assessments for fulfilling the obligations set out in this Article*.

## **Amendment 83**

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

Text proposed by the Commission

### Amendment

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

### **Amendment 84**

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

Text proposed by the Commission

### Amendment

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

PE731.563v02-00 496/665 RR\1279290EN.docx

# Proposal for a regulation Article 40 – paragraph 1

Text proposed by the Commission

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

### Amendment 86

Proposal for a regulation Article 40 – paragraph 1 a (new)

Text proposed by the Commission

### Amendment

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

### Amendment

- 1a. 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, 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, trustworthy and respect Union values and strengthen the Union's digital sovereignty;
- b) take into account the general principles for trustworthy AI set out in Article 4a;
- c) promote investment and innovation in AI, as well as competitiveness and growth of the Union market;
- d) enhance multistakeholder governance, representative of all relevant

European stakeholders (e.g. industry, SMEs, civil society, social partners, researchers);

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

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

1b. The Commission shall issue standardisation requests covering all requirements of this Regulation in accordance with Article 10 of Regulation (EU) No1025/2012 before the date of entry into force of this Regulation.

### Amendment 87

Proposal for a regulation Article 52 – title

Text proposed by the Commission

Text proposed by the Commission

Transparency obligations *for certain AI* systems

**Amendment 88** 

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

Amendment

Transparency obligations

## Amendment

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that the AI system, the provider itself or the user informs the natural person exposed to an AI system that they are interacting with an AI system in a timely, clear and intelligible manner, unless this is obvious from the circumstances and the context of use.

PE731.563v02-00 498/665 RR\1279290EN.docx

offences, unless those systems are available for the public to report a criminal offence

> Where appropriate and 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, as well as the existing rights and processes that, according to Union and national law, allow natural persons or their representatives to object against the application of such systems to them and to seek judicial redress against decisions taken by or harm caused by AI systems, including their right to seek an explanation. 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 89**

# 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

Users of an emotion recognition system or a biometric categorisation system which is not prohibited pursuant to Article 5 shall inform in a timely, clear and intelligible manner of the operation of the system the natural persons exposed thereto and obtain their consent prior to the processing of their biometric and other personal data in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.

## Proposal for a regulation Article 52 – paragraph 3 – subparagraph 1

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 *text*, 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 in an appropriate, timely, clear and visible manner that the content has been artificially generated or manipulated, as well as, whenever possible, the name of the natural or legal person that generated or manipulated it. 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.

### **Amendment 91**

# Proposal for a regulation Article 52 – paragraph 3 – subparagraph 2

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

3a. Paragraph 3 shall not apply where the use of an AI system that generates or manipulates text, audio or visual content is authorized by law or if 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. Where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video games visuals and

PE731.563v02-00 500/665 RR\1279290EN.docx

analogous work or programme, transparency obligations set out in paragraph 3 are limited to disclosing of the existence of such generated or manipulated content in an appropriate clear and visible manner that does not hamper the display of the work and disclosing the applicable copyrights, where relevant. It shall also not prevent law enforcement authorities from using AI systems intended to detect deep fakes and prevent, investigate and prosecute criminal offences linked with their use

### **Amendment 92**

Proposal for a regulation Article 52 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The information referred to in paragraphs 1 to 3 shall be provided to the natural persons at the latest at the time of the first interaction or exposure. It shall be accessible to vulnerable persons, such as persons with disabilities or children, complete, where relevant and appropriate, with intervention or flagging procedures for the exposed natural person taking into account the generally acknowledged state of the art and relevant harmonised standards and common specifications.

### **Amendment 93**

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 an independent body with its own legal personality to promote a trustworthy, effective and competitive internal market

for artificial intelligence. The Board shall be organised in a way that guarantees the independence, objectivity and impartiality of its activities and shall have a secretariat, a strong mandate as well as sufficient resources and skilled personnel at its disposal for assistance in the proper performance of its tasks laid down in Article 58.

### **Amendment 94**

# 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 Member States, when implementing Union law related to artificial intelligence as well as cooperate with the providers and users of AI systems in order to:

## **Amendment 95**

# 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) *promote and support* the effective cooperation of the national supervisory authorities and the Commission;

## **Amendment 96**

# Proposal for a regulation Article 56 – paragraph 2 – point c

Text proposed by the Commission

(c) assist the national supervisory

Amendment

(c) assist the *Commission*, national

PE731.563v02-00 502/665 RR\1279290EN.docx

authorities and *the Commission* in ensuring the consistent application of this Regulation.

supervisory authorities and other national 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 97

Proposal for a regulation Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) assist providers and users of AI systems to meet the requirements of this Regulation, as well as those set out in present and future Union legislation, in particular SMEs and start-ups.

**Amendment 98** 

Proposal for a regulation Article 56 – paragraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(cb) provide particular oversight, monitoring and regular dialogue with the providers of general purpose AI systems about their compliance with this Regulation. Any such meeting shall be open to national supervisory authorities, notified bodies and market surveillance authorities to attend and contribute;

**Amendment 99** 

Proposal for a regulation Article 56 – paragraph 2 – point c c (new)

Text proposed by the Commission

Amendment

(cc) propose amendments to Annex I and III.

RR\1279290EN.docx 503/665 PE731.563v02-00

Proposal for a regulation Article 56 – paragraph 2 a (new)

Text proposed by the Commission

### Amendment

2a. The Board shall act as a reference point for advice and expertise for Union institutions, bodies, offices and agencies as well as for other relevant stakeholders on matters related to artificial intelligence.

### **Amendment 101**

Proposal for a regulation Article 57 – title

Text proposed by the Commission

Structure of the Board

Amendment

**Mandate and** structure of the Board

## **Amendment 102**

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. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them. *The Board composition shall be gender balanced.* 

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 DirectorGeneral of the Joint Research Centre, and
the presidents of the European Committee

PE731.563v02-00 504/665 RR\1279290EN.docx

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.

#### Amendment 103

## 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 with the assistance of its secretariat. 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 subgroups as appropriate for the purpose of examining specific questions.

#### Amendment 104

# 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 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.

## 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 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, trade unions, representatives of affected persons, academia and researchers, testing and experimentation facilities and standardisation organisations, to attend its meetings in order to ensure accountability and appropriate participation of external actors. The agenda and the minutes of its meetings shall be published online. The Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

## **Amendment 106**

Proposal for a regulation Article 57 – paragraph 4 a (new)

Text proposed by the Commission

#### Amendment

4a. Without prejudice to paragraph 4, the Board's Secretariat shall organise four additional meetings between the Board and the High Level Expert Group on Trustworthy AI to allow them to share their practical and technical expertise every quarter of the year.

**Amendment 107** 

Proposal for a regulation Article 58 – paragraph 1 – introductory part

PE731.563v02-00 506/665 RR\1279290EN.docx

## 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 Member States* in the context of Article 56(2), the Board shall in particular:

#### **Amendment 108**

## Proposal for a regulation Article 58 – paragraph 1 – point a

Text proposed by the Commission

(a) collect and share expertise and best practices among Member States;

#### Amendment

(a) collect and share expertise and best practices among Member States, including on the promotion of AI literacy and awareness raising initiatives on Artificial Intelligence and this Regulation;

## **Amendment 109**

Proposal for a regulation Article 58 – paragraph 1 – point a a (new)

Text proposed by the Commission

#### Amendment

(aa) promote and support the cooperation among national supervisory authorities and the Commission;

## **Amendment 110**

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,

RR\1279290EN.docx 507/665 PE731.563v02-00

*and* functioning of regulatory sandboxes referred to in Article 53;

## **Amendment 111**

# Proposal for a regulation Article 58 – paragraph 1 – point c – introductory part

Text proposed by the Commission

Amendment

- (c) issue *opinions*, recommendations or written contributions on matters related to the implementation of this Regulation, in particular
- (c) issue *guidelines*, recommendations or written contributions on matters related to the implementation of this Regulation, in particular

## **Amendment 112**

Proposal for a regulation Article 58 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission

Amendment

(iia) on the provisions related to post market monitoring as referred to in Article 61,

## **Amendment 113**

Proposal for a regulation Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) 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.

## **Amendment 114**

Proposal for a regulation Article 58 – paragraph 1 – point c – point iii b (new)

PE731.563v02-00 508/665 RR\1279290EN.docx

(iiib) on activities and decisions of Member States regarding post-market monitoring, information sharing, market surveillance referred to in Title VIII;

#### **Amendment 115**

Proposal for a regulation Article 58 – paragraph 1 – point c – point iii c (new)

Text proposed by the Commission

Amendment

(iiic) on 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 Articles 9(3), 13(1), 14(4), 23a(3) or 52(3a), 'foreseeable risks' referred to in Articles 9(2), point (a), and 'foreseeable misuse' referred to in Article 3(13), Article 9(2), point (b), Article 9(4), Article 13(3), point (b)(iii), Article 14(2) and Article 23a(3c);

#### **Amendment 116**

Proposal for a regulation Article 58 – paragraph 1 – point c – point iii d (new)

Text proposed by the Commission

Amendment

(iiid) on the verification of the alignment with the legal acts listed in Annex II, including with the implementation matters related to those acts.

### **Amendment 117**

Proposal for a regulation Article 58 – paragraph 1 – point c – point iii e (new) Text proposed by the Commission

Amendment

(iiie) on the respect of the general principles applicable to all AI systems referred to in Article 4a;

**Amendment 118** 

Proposal for a regulation Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) carry out annual reviews and analyses of the complaints sent to and findings made by national supervisory 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 that are not adequately addressed by this Regulation;

**Amendment 119** 

Proposal for a regulation Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) carry out biannual horizontal scanning and foresight exercises to extrapolate the impact that scientific developments, trends and emerging issues can have on the Union;

Amendment 120

Proposal for a regulation Article 58 – paragraph 1 – point c c (new)

PE731.563v02-00 510/665 RR\1279290EN.docx

Text proposed by the Commission

Amendment

(cc) annually publish recommendations to the Commission, in particular on the categorisation of prohibited practices, high-risk systems, and codes of conduct for AI systems that are not classified as high-risk;

## **Amendment 121**

Proposal for a regulation Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(cd) encourage and facilitate the drawing up of codes of conduct as referred to in Article 69;

## **Amendment 122**

Proposal for a regulation Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(ce) coordinate among national competent authorities and make sure that the consistency mechanism in Article 59a(3) is observed, in particular for all major cross-border cases;

## **Amendment 123**

Proposal for a regulation Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(cf) 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).

## **Amendment 124**

Proposal for a regulation Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission

Amendment

- (cg) provide guidance material to providers and users regarding the compliance with the requirements set out in this Regulation. In particular, it shall issue guidelines:
- i) for the trustworthy AI technical assessment referred to in Article 4a,
- ii) for the methods for performing the conformity assessment based on internal control referred to Article 43;
- iii) to facilitate compliance with the reporting of serious incidents or malfunctioning referred to in Article 62;
- iv) on any other concrete procedures to be performed by providers and users when complying with this Regulation, in particular those regarding the documentation to be delivered to notified bodies and methods to provide authorities with other relevant information.

## **Amendment 125**

Proposal for a regulation Article 58 – paragraph 1 – point c h (new)

Text proposed by the Commission

Amendment

(ch) provide specific guidance to support SMEs and start-ups in complying with the obligations set out in this Regulation;

PE731.563v02-00 512/665 RR\1279290EN.docx

Proposal for a regulation Article 58 – paragraph 1 – point c i (new)

Text proposed by the Commission

Amendment

(ci) raise awareness and provide guidance material to providers and users regarding the compliance with the requirement to put in place tools and measures to ensure a sufficient level of AI literacy in line with Article 4b;

## **Amendment 127**

Proposal for a regulation Article 58 – paragraph 1 – point c j (new)

Text proposed by the Commission

Amendment

(cj) contribute to the Union efforts to cooperate with third countries and international organisations in view of promoting a common global approach towards trustworthy AI;

## **Amendment 128**

Proposal for a regulation Article 58 – paragraph 1 – point c k (new)

Text proposed by the Commission

Amendment

(ck) issue yearly reports on the implementation of this Regulation, including an assessment of its impact on economic operators;

## **Amendment 129**

Proposal for a regulation Article 58 – paragraph 1 – point c l (new)

# (cl) provide guidance on the governance of research and development.

#### Amendment 130

Proposal for a regulation Article 59 – title

Text proposed by the Commission

Designation of national *competent* authorities

Amendment

Designation of national *supervisory* authorities

## **Amendment 131**

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.

## **Amendment 132**

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

## Amendment

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

PE731.563v02-00 514/665 RR\1279290EN.docx

State has organisational and administrative reasons to designate more than one authority.

competent authorities designated under those legal acts shall continue to lead the 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.

#### **Amendment 133**

## 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 competent 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. In addition, the central contact point of each Member State should be contactable through electronic communications means.

#### **Amendment 134**

# 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

#### 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

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.

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.

#### Amendment 135

Proposal for a regulation Article 59 – paragraph 4 a (new)

Text proposed by the Commission

#### Amendment

4a. The national competent authority 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.

### **Amendment 136**

Proposal for a regulation Article 59 – paragraph 4 b (new)

Text proposed by the Commission

## Amendment

4b. Any information and documentation obtained by the national supervisory authority pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Amendment 137

Proposal for a regulation Article 59 – paragraph 5

PE731.563v02-00 516/665 RR\1279290EN.docx

## 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.

#### **Amendment 138**

## 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 *supervisory* authorities.

## **Amendment 139**

# 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 national authorities under that Union legislation shall be consulted as appropriate.

## **Amendment 140**

# 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 141**

Proposal for a regulation Article 59 a (new)

Text proposed by the Commission

#### 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*.

#### Amendment

#### Article 59a

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. In the event of a cross-border case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the provider's or user's place of central administration in the Union is established or where the authorised representative is appointed, shall be competent to act as lead national supervisory authority for a cross-border case that involves an AI-system.
- 3. In the case referred to in paragraph 2, the national supervisory authorities shall cooperate, exchange all relevant information with each other in due time, provide mutual assistance and execute joint operations. National

PE731.563v02-00 518/665 RR\1279290EN.docx

supervisory authorities shall cooperate in order to reach a consensus.

- 4. In case of a serious disagreement between two or more national supervisory authorities, the lead national supervisory authority shall notify the Board and communicate without delay all relevant information related to the case to the Board.
- 5. The Board shall within three months of the notification referred to in paragraph 4, issue a binding decision to the national supervisory authorities.

#### **Amendment 142**

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 malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than 72 hours after the provider becomes aware of the serious incident or of the malfunctioning.

## **Amendment 143**

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 or malfunctioning is also to be reported by providers to comply with obligations laid down by other acts of Union law. In that case, the authorities competent under those acts of Union law

shall forward the received report to the national supervisory authority designated under this Regulation.

#### **Amendment 144**

## 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, the Board and the Member States shall encourage and facilitate the drawing up of codes of conduct intended, including where they are drawn up in order to demonstrate how AI systems respect the principles set out in Article 4a and can thereby be considered trustworthy, to foster the voluntary application to AI systems other than highrisk 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 145**

# 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

#### Amendment

2. Codes of *conduct* intended to foster the voluntary *compliance with the principles underpinning trustworthy AI systems, shall, in particular:* 

PE731.563v02-00 520/665 RR\1279290EN.docx

achievement of those objectives.

- (a) aim for a sufficient level of AI literacy among their staff and other persons dealing with the operation and use of AI systems in order to observe such principles;
- (b) assess to what extent their AI systems may affect vulnerable persons or groups of persons, including children, the elderly, migrants and persons with disabilities or whether measures could be put in place in order to increase accessibility, or otherwise support such persons or groups of persons;
- (c) consider the way in which the use of their AI systems may have an impact or can increase diversity, gender balance and equality;
- (d) have regard to whether their AI systems can be used in a way that, directly or indirectly, may residually or significantly reinforce existing biases or inequalities;
- (e) reflect on the need and relevance of having in place diverse development teams in view of securing an inclusive design of their systems;
- (f) give careful consideration to whether their systems can have a negative societal impact, notably concerning political institutions and democratic processes;
- (g) evaluate how AI systems can contribute to environmental sustainability and in particular to the Union's commitments under the European Green Deal and the European Declaration on Digital Rights and Principles.

**Amendment 146** 

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 both, including with the involvement of users and any interested stakeholders, including scientific researchers, and their representative organisations, in particular trade unions, and consumer organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems. Providers adopting codes of conduct will designate at least one natural person responsible for internal monitoring.

## **Amendment 147**

# 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.

## **Amendment 148**

Proposal for a regulation Article 69 a (new)

Text proposed by the Commission

Amendment

## Article 69a

Right to lodge a complaint before 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

PE731.563v02-00 522/665 RR\1279290EN.docx

- 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, fundamental rights, their right to an explanation or any other of their rights deriving from the obligations laid down in this Regulation have been breached by the provider or the user of an AI system falling within the scope of this Regulation. Such 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. 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.

# Proposal for a regulation Article 69 b (new)

Text proposed by the Commission

Amendment

## Article 69b

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 or non-judicial remedy, including repair, replacement, price reduction, contract termination, reimbursement of the price paid or compensation for material and immaterial damages, against a legally binding decision of a national supervisory authority concerning them that infringes their rights.
- 2. Without prejudice to any other administrative or non-judicial remedy, each affected person 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.

**Amendment 150** 

Proposal for a regulation Article 69 c (new)

PE731.563v02-00 524/665 RR\1279290EN.docx

## Article 69c

## Right to an explanation

- Any affected persons subject to a decision taken by a provider or an user, on the basis of an output from an AI system falling within the scope of this Regulation, which produces legal effects that they consider to adversely impact their health, safety, fundamental rights, socio-economic well-being or any other of their rights deriving from the obligations laid down in this Regulation, shall receive from the provider or the user, at the time when the decision is communicated, a clear and meaningful explanation pursuant to Article 13(1) on the role of the AI system in the decision-making procedure, the main parameters of the decision taken and on the related input data.
- 2. Paragraph 1 shall not apply to the use of AI systems:
- (a) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law, which lays down other appropriate safeguards for the affected persons' rights, freedoms and legitimate interests; or
- (b) where the affected person has given free, explicit, specific and informed consent not to receive an explanation. The affected person shall have the right to withdraw his or her consent not to receive an explanation at any time. Prior to giving consent, the affected person shall be informed thereof. It shall be as easy to withdraw as to give consent.

### **Amendment 151**

# Proposal for a regulation Article 69 d (new)

Text proposed by the Commission

Amendment

## Article 69d

## Representative actions

1. The following is added to Annex I of Directive (EU) 2020/1828 on Representative actions for the protection of the collective interests of consumers:

"Regulation xxxx/xxxx of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts".

#### **Amendment 152**

Proposal for a regulation TITLE X – title

Text proposed by the Commission

Amendment

CONFIDENTIALITY AND PENALTIES

CONFIDENTIALITY, *REMEDIES* AND PENALTIES

## **Amendment 153**

Proposal for a regulation Article 84 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Within [three years after the date of application of this Regulation referred to in Article 85(2)], the Commission shall evaluate the effectiveness of the Board to carry out its tasks and assess whether an EU Agency would be best placed to ensure an effective and harmonised implementation of this Regulation.

PE731.563v02-00 526/665 RR\1279290EN.docx

Proposal for a regulation Annex VIII – point 5 a (new)

Text proposed by the Commission

Amendment

5a. The outcome of the trustworthy technology assessment;

# PROCEDURE - COMMITTEE ASKED FOR OPINION

Title	Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts		
References	COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)		
Committees responsible Date announced in plenary	IMCO 7.6.2021	LIBE 7.6.2021	
Opinion by Date announced in plenary	JURI 7.6.2021		
Associated committees - date announced in plenary	16.12.2021		
Rapporteur for the opinion Date appointed	Axel Voss 10.1.2022		
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021		
Discussed in committee	26.1.2022	15.3.2022	28.3.2022
Date adopted	5.9.2022		
Result of final vote	+: -: 0:	17 1 0	

# FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

17	+
ID	Jean-François Jalkh
NI	Sabrina Pignedoli
PPE	Pascal Arimont, Angelika Niebler, Luisa Regimenti, Axel Voss, Elissavet Vozemberg-Vrionidi, Marion Walsmann, Javier Zarzalejos
RENEW	Ilana Cicurel, Pascal Durand, Karen Melchior, Adrián Vázquez Lázara
S&D	René Repasi, Tiemo Wölken, Lara Wolters
VERTS/ALE	Heidi Hautala

1	-
THE LEFT	Cornelia Ernst

0	0

# Key to symbols:

+ : in favour- : against0 : abstention

# OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

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

on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

(COM(2021)0206 - C9-0146/2021 - 2021/0106(COD))

Rapporteur for opinion: Susana Solís Pérez

## SHORT JUSTIFICATION

The proposal for Regulation of the European Parliament and the Council laying down harmonized rules on Artificial Intelligence (hereinafter "AI Act") is part of the broader agenda to boost Europe in the digital age and achieve its environmental and climate objectives. This stems from the fact that AI currently plays a role in all aspects of European daily life activities.

AI systems will become more and more embedded into products and services therefore requiring a horizontal legislative approach as set out in the AI Act. The Rapporteur is fully aligned with this as she considers that we must establish the common rules to provide a crosscutting approach to all sectors, including the healthcare sector. By doing so, the European Union has a chance to lead and set the standards of AI worldwide, as it has already done with data protection through GDPR. The EU could also become a global leader in niche sectors that require a very forward-looking perspective such as the regulation of neurological rights.

Overall the AI act should preserve European values, facilitating the distribution of AI's benefits across society, protecting individuals, companies and the environment from risks while boosting innovation and employment and making Europe a leader in the field.

In this regard, the Rapporteur wants to emphasize the importance of sandboxes in certain areas (e.g. Health) and how it could be extended to other areas such as Hospitals, Health Authorities and research centers in order to reinforce and expand the leading position of the health system in all the Member States and at EU level. Health is wealth. By applying AI in health using interoperable health data we could further increase this wealth from health systems to society at large. The Rapporteur also highlights the potential implications of AI systems in mental health.

The Rapporteur for the opinion deems that the proposal insufficiently anticipates the risks of not having a common and consistent regulatory approach.

As a horizontal legislative initiative, the proposed AI Act is expected to intersect with several regulations currently in place (e.g GDPR or MDR) and several legislative initiatives that might intersect in the future such as the European Health Data Space. All these initiatives should be aligned with the AI Act to ensure a common and consistent regulatory approach therefore avoiding duplication of functions or discoordination among bodies and authorities at both the EU and Member State level.

# The Rapporteur for the opinion is concerned that the AI Act does not provide sufficient protection to the environment.

The Special Eurobarometer 513 Climate change published in 2021 shows that tackling climate and environmental-related challenges is one of the main concerns for European citizens. Therefore, the Rapporteur proposes that the AI Act shall include the environment among the areas that require a high level of protection. In order to do so, the environment has been included in all the recitals and articles together with health, safety and the protection of fundamental rights. This will entail the classification as "high risk AI" of all those systems that can have major negative implications on the environment. At the same time, the Rapporteur has reinforced the right to proper redress mechanisms in case of negative environmental impacts as set out in the Aarhus Convention, and has set the principle of "Do no significant harm" as established in the Taxonomy Regulation as a limit to ensure that AI systems abide with the EU's high level of environmental standards and rights.

# The Rapporteur for the opinion considers that the AI Act shall not just cover users but must expand its scope to end recipients too.

Many of the applications mentioned in the proposed AI Act will involve not just users but end recipients. In the case of healthcare applications this distinction is crucial as there is a clear differentiation between the intended use and capabilities of patients and doctors. Therefore, the draft report now includes a new definition of end recipients and grants them the appropriate degree of transparency and provision of specific information.

## **AMENDMENTS**

The Committee on the Environment, Public Health and Food Safety calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to take into account the following amendments:

#### Amendment 1

# 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 AIbased 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

The purpose of this Regulation is to (1) improve the functioning of the internal market by laying down a uniform legal framework for the *design*, development, marketing and use of artificial intelligence and of sustainable and green artificial intelligence in conformity with Union priorities and values while minimising any risk of adverse and discriminatory impacts on people and adverse impacts on the environment. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of biodiversity, the climate and the environment, 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 design, development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

#### Amendment 2

Proposal for a regulation Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) This Regulation should serve as a basis to promote health, wellbeing, prevent diseases, and foster a supportive environment for healthier lifestyles in a

PE731.563v02-00 532/665 RR\1279290EN.docx

sustainable and climate neutral way and, in particular, facilitate the achievement of the UN Sustainable Development Goals, the Paris Agreement and net-zero transition by 2050 across different sectors. Member States can establish additional requirements other than those established under this Regulation provided they are justified for reasons of public interest, the protection of legal rights, the protection of the climate, the environment and biodiversity.

#### Amendment 3

# Proposal for a regulation Recital 1 b (new)

Text proposed by the Commission

#### Amendment

(1b) This Regulation should preserve the values of the Union facilitating the distribution of artificial intelligence benefits across society, protecting individuals, companies and the environment from risks while boosting innovation and employment and making Europe a leader in the field.

#### **Amendment 4**

# 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

## 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.

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, end users and end recipients 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 5

# Proposal for a regulation Recital 3

Text proposed by the Commission

(3) Artificial intelligence is a fast evolving family of technologies that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally

## Amendment

(3) Artificial intelligence is a fast evolving family of technologies that can contribute to a wide array of economic, *environmental* and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support

PE731.563v02-00 534/665 RR\1279290EN.docx

beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation. socially and environmentally beneficial outcomes, for example in food safety, by reducing the use of pesticides, the protection of nature, the conservation and restoration of biodiversity and ecosystems, environmental monitoring, access to and provision of medicines and healthcare, including mental health, carbon farming, education and training, infrastructure management, crisis management, management of natural disasters, energy, sustainable transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

#### Amendment 6

# 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, whether individual, societal or environmental. Such harm might be material or immaterial, present or future.

## Amendment 7

# Proposal for a regulation Recital 4 a (new)

Text proposed by the Commission

#### Amendment

(4a) In its White Paper on "Artificial Intelligence - A European approach to excellence and trust" of 19 February 2020, the Commission recalled that artificial intelligence can contribute to finding solutions to some of the most pressing societal challenges, including the

RR\1279290EN.docx 535/665 PE731.563v02-00

fight against climate change, biodiversity loss and environmental degradation and highlighted the potential benefits and risks of artificial intelligence in relation to safety, health and wellbeing of individuals.

## Amendment 8

Proposal for a regulation Recital 4 b (new)

Text proposed by the Commission

#### Amendment

Tackling climate change and (4b)environmental-related challenges and reaching the objectives of the Paris Agreement are at the core of the Communication of the Commission on the "European Green Deal", adopted on 11 December 2019, where the Commission recalled the role of digital technologies such as artificial intelligence, 5G, cloud and edge computing and the internet of things in achieving a sustainable future and to accelerate and maximise the impact of policies to deal with climate change mitigation and adaptation, protect the environment and address biodiversity loss.

## Amendment 9

Proposal for a regulation Recital 4 c (new)

Text proposed by the Commission

#### Amendment

(4c) AI applications can bring environmental and economic benefits and strengthen predictive capabilities that contribute to the fight against climate change, to meeting the Sustainable Development Goals (SDGs) and to achieving our target of becoming the first climate-neutral continent. In this sense, the use of AI has the potential to reduce

PE731.563v02-00 536/665 RR\1279290EN.docx

global greenhouse gas emissions by up to 4 % by 2030. It has also been estimated that ICT technologies are capable of reducing ten times more greenhouse gas emissions than their own footprint <sup>1a</sup>. In terms of environment, artificial intelligence has a strong potential to solve environmental issues such as reducing resource consumption, promoting decarbonisation, boosting the circular economy, balancing supply and demand in electricity grids or optimising logistic routes. Artificial intelligence also has the potential to contribute to strengthening environmental administration and governance by facilitating administrative decisions related to environmental heritage management, monitoring violations and environmental fraud, and encouraging citizen participation in biodiversity conservation initiatives. Moreover, the analysis of large volumes of data can lead to a better understanding of environmental challenges and a better monitoring of trends and impacts. The intelligent management of large volumes of information related to the environment also provides solutions for better environmental planning, decision-making and monitoring of environmental threats and can inform and encourage environmentally sustainable business, providing better information to reorient sustainable decision-making in different business models, and thereby improving the efficiency of resource, energy and material use through smart-Industry initiatives and machine to machine (M2M) and internet of things (IoT) technologies.

1a.

https://www.europarl.europa.eu/cmsdata/231979/Working%20Paper%20-%20AIDA%20Hearing%20on%20AI%20 and%20Green%20Deal.pdf

# Proposal for a regulation Recital 4 d (new)

Text proposed by the Commission

Amendment

(4d)The predictive analytics capabilities provided by models based on artificial intelligence can support a better maintenance of energy systems and infrastructure, as well as anticipate the patterns of society's interaction with natural resources, thus facilitating better resource management. Artificial intelligence can serve in climate change mitigation for example through the European Union's Earth observation programme Copernicus that has the potential to be the programme needed to acquire accurate scientific information that secures science-based decisionmaking and implementation of the Union's climate, biodiversity and other environmental policies. The United Kingdom's withdrawal from the European Union has caused a significant funding gap to the aforementioned Copernicus programme, which endangers the whole future of Copernicus and which needs to be acutely solved by guaranteeing sufficient funds as well as data processing support so that advanced and automatized technology and artificial intelligence based monitoring and analysing of all central environmental indicators will be guaranteed in the future. In addition, traditional identification of species has been time consuming and costly, which hinders real time biodiversity assessments. The integration of AI systems has the potential to move away from manual sorting and identification of species, which can play a role in animal conservation by allowing authorities to quickly identify, observe and monitor endangered species populations and help inform additional measures if needed for conservation purposes.

PE731.563v02-00 538/665 RR\1279290EN.docx

# Proposal for a regulation Recital 4 e (new)

Text proposed by the Commission

## Amendment

(4e) 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 contributes 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 infrastructures.

#### **Amendment 12**

Proposal for a regulation Recital 4 f (new)

Text proposed by the Commission

#### Amendment

(4f) Despite the high potential 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 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.

## **Amendment 13**

Proposal for a regulation Recital 4 g (new)

Text proposed by the Commission

Amendment

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 date centres including information on the energy

PE731.563v02-00 540/665 RR\1279290EN.docx

efficiency of algorithms to establish a sustainability indicator for artificial intelligence technologies. A European code of conduct for data centre 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 freshwater.

#### Amendment 14

# Proposal for a regulation Recital 5

Text proposed by the Commission

(5) A Union legal framework laving 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 Council<sup>33</sup>, and it ensures the protection of ethical principles, as specifically requested by the European Parliament<sup>34</sup>.

#### Amendment

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the *design*, development, use and uptake of sustainable and green artificial intelligence in the internal market aligned with the European Green Deal objectives, that at the same time meets a high level of protection of public interests, such as health and safety, environment and climate change, food security 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, non-biased, trustworthy and ethical artificial intelligence, as stated by the European Council<sup>[33]</sup>, and it ensures the protection of ethical principles, as specifically requested

RR\1279290EN.docx 541/665 PE731.563v02-00

by the European Parliament<sup>[34]</sup>.

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

#### **Amendment 15**

# 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 standalone 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, such as neurotechnology, which may put mental privacy at risk and require legislative proposals to protect neurodata and other sensitive health data. 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

PE731.563v02-00 542/665 RR\1279290EN.docx

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

<sup>&</sup>lt;sup>34</sup> 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).

<sup>&</sup>lt;sup>34</sup> 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).

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 16

# 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 17

# Proposal for a regulation Recital 13 c (new)

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, fundamental rights *or the environment*, 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

(13c) Artificial intelligence can unlock solutions in the health sector that could save millions of lives, respond to unmet needs, improve our standard of living and improve patient care and health outcomes, especially in diagnosis, prognosis and treatment, patient engagement, adherence, management and follow-up, clinical decision-making, including predictive analytics, screening and optimization of clinical pathways, and pathology. Artificial intelligence can also improve prevention strategies, health system management and in the organization and provision of health services and medical care, including health promotion and disease prevention interventions. It also has the potential to

foster the competitiveness of stakeholders and to improve the cost-effectiveness and sustainability of health services and medical care. The Union has the potential to become a leader in the application of artificial intelligence in the healthcare sector.

#### **Amendment 18**

# Proposal for a regulation Recital 16

Text proposed by the Commission

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 humanmachine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

#### Amendment

The placing on the market, putting (16)into service or use of certain AI systems intended to distort human behaviour. whereby physical, psychological harms or disruption of the sense of oneself 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 or remove ultimate control over personal decision-making, with unknown manipulation from external neurotechnologies. 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 humanmachine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

PE731.563v02-00 544/665 RR\1279290EN.docx

#### Amendment 19

### Proposal for a regulation Recital 27

Text proposed by the Commission

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

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 climate priorities, environmental imperatives and 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, greenhouse gas emissions, crucial environmental parameters like biodiversity or soil pollution and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

# **Amendment 20**

Proposal for a regulation Recital 27 a (new)

Text proposed by the Commission

### Amendment

(27a) According to the definition of the World Health Organisation (WHO), "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." In order to improve the health of the population in the Union and reduce health inequalities, it is essential not to focus only on physical health. Digital technologies and especially artificial intelligence can have a direct negative impact on mental health. At the same time, the full potential of artificial

intelligence should be unleashed in the development of prediction, detection, and treatment solutions for mental health. The right to physical and mental health is a fundamental human right and universal health coverage is a SDG that all signatories have committed to achieve by 2030.

#### **Amendment 21**

# 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-

#### Amendment

(28)AI systems could produce adverse outcomes to health and safety of persons or to the environment, 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. Digital health should not dehumanise care nor diminish the doctor-patient relationship, but should assist doctors in diagnosing or treating patients more effectively, while keeping in mind the necessary human oversight and abiding by relevant data *protection rules*. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter

PE731.563v02-00 546/665 RR\1279290EN.docx

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.

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 and health data, freedom of expression and information, freedom of assembly and of association, and nondiscrimination, 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 to the environment

#### Amendment 22

Proposal for a regulation Recital 28 a (new)

Text proposed by the Commission

Amendment

(28a) In terms of health and patients' rights, AI systems can play a major role in improving the health of individual patients and the performance of public health systems. However, when artificial intelligence is deployed in the context of health, patients may be exposed to potential specific risks that could lead to physical or psychological harm, for

example, when different biases related to age, ethnicity, sex or disabilities in algorithms lead to incorrect diagnoses. The lack of transparency around the functioning of algorithms also makes it difficult to provide patients with the relevant information they need to exercise their rights, such as informed consent. In addition, artificial intelligence's reliance on large amounts of data, many of them being personal data, may affect the protection of medical data, due to patients' limited control over the use of their personal data and the cybersecurity vulnerabilities of AI systems. All of this means that special caution must to be taken when artificial intelligence is applied in clinical or healthcare settings. In order to improve the health outcomes of the population in Member States, it is essential to have a clear liability framework in place for artificial intelligence medical applications and medicine development.

#### **Amendment 23**

Proposal for a regulation Recital 28 b (new)

Text proposed by the Commission

#### Amendment

(28b) AI systems not covered by Regulation (EU) 2017/745 with an impact on health or healthcare should be classified as high-risk and be covered by this Regulation. Healthcare is one of the sectors where many artificial intelligence applications are being deployed in the Union and is a market posing potential high risk to human health. Regulation (EU) 2017/745 only covers medical devices and software with an intended medical purpose, but excludes many artificial intelligence applications used in health, like artificial intelligence administrative and management systems used by healthcare professionals in hospitals or other healthcare setting and

by health insurance companies and many fitness and health apps which provides artificial intelligence powered recommendations. These applications may present new challenges and risks to people, because of their health effects or the processing of sensitive health data. In order to control this, potential specific risks that could lead to any physical or psychological harm or the misuse of sensitive health data, these AI systems should be classified as high-risk.

#### Amendment 24

# Proposal for a regulation Recital 31

Text proposed by the Commission

The classification of an AI system (31)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 Council<sup>47</sup> and Regulation (EU) 2017/746 of the European Parliament and of the Council<sup>48</sup>, where a third-party conformity assessment is provided for medium-risk and high-risk products.

#### Amendment

The classification of an AI system (31)as high-risk pursuant to this Regulation should not, unless duly justified, 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 Council<sup>47</sup> and Regulation (EU) 2017/746 of the European Parliament and of the Council<sup>48</sup>, where a third-party conformity assessment is provided for medium-risk and high-risk products. To ensure consistency and legal clarity, where the provided risk-based system already takes into account potential associated risks, artificial intelligence components should continue to be assessed as part of the overall device.

<sup>&</sup>lt;sup>47</sup> 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

<sup>&</sup>lt;sup>47</sup> 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).

<sup>48</sup> 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).

#### **Amendment 25**

# Proposal for a regulation Recital 32

Text proposed by the Commission

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 26**

# 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

1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

<sup>48</sup> 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).

#### Amendment

As regards stand-alone AI systems, (32)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, safety or the fundamental rights of persons or the environment, 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

(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

PE731.563v02-00 550/665 RR\1279290EN.docx

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. operation of road traffic, the supply of water and gas, healthcare systems, natural or anthropogenic disaster control mechanisms, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons and environment at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

#### Amendment 27

### 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

#### 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, including healthcare, 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, healthcare 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

RR\1279290EN.docx 551/665 PE731.563v02-00

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, nondiscrimination, 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 highrisk since they make decisions in very critical situations for the life and health of persons and their property.

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, health and wellbeing, 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, disease prevention, diagnosis, control and treatment should also be classified as highrisk since they make decisions in very critical situations for the life and health of persons and their property or the environment

#### **Amendment 28**

# 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

#### 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

PE731.563v02-00 552/665 RR\1279290EN.docx

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.

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, including the right to access to justice for environmental matters as established in the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters ("tAarhus Convention") applicable to the Union institutions and bodies through Regulation 1367/2006 of the European Parliament and of the Council\* 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.

\* Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.09.2006, p. 13).

#### Amendment 29

# Proposal for a regulation Recital 40

Text proposed by the Commission

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

#### Amendment

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, as well as related serious ethical concerns regarding machine autonomy and decision-making, 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

PE731.563v02-00 554/665 RR\1279290EN.docx

anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

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 30

# Proposal for a regulation Recital 43

Text proposed by the Commission

(43) Requirements should apply to highrisk 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 highrisk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users and end recipients, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights and more widely for the climate and the environment, 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. To avoid any potential misalignment or duplication, the Commission should clearly determine where any relevant sectoral legislation may take precedence concerning data governance and any associated management practices or quality criteria.

#### Amendment 31

Proposal for a regulation Recital 43 a (new)

Text proposed by the Commission

Amendment

(43a) These requirements should also take into account the international environmental and human rights principles and instruments including the Aarhus Convention, Resolution 48/13 adopted by the Human Rights Council on 8 October 2021 on the human right to a clean, healthy and sustainable environment, as well as international climate commitments outlined in the 2018 IPCC Special Report to limit global average temperatures to 1,5 degrees.

#### Amendment 32

# Proposal for a regulation Recital 43 b (new)

Text proposed by the Commission

#### Amendment

(43b) The Union commits to progressing towards the recognition of the right to a clean, healthy and sustainable environment, as laid out in Resolution 48/13 of the UN Human Rights Council.

### **Amendment 33**

# 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

#### 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

PE731.563v02-00 556/665 RR\1279290EN.docx

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 shouldbe 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 highrisk AI systems.

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, that is, to ensure algorithmic non-discrimination, 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 highrisk AI systems.

complete in view of the intended purpose

### **Amendment 34**

# 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

#### Amendment

(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, research and scientific institutes, health authorities, hospitals, testing experimentation facilities and researchers, should be able to have increased access and use *of* 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,

RR\1279290EN.docx 557/665 PE731.563v02-00

data space will facilitate nondiscriminatory 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.

validation and testing of AI systems. For example, in health, the European health data space will facilitate nondiscriminatory 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. Artificial intelligence applications for medicines and healthcare should support the interoperability of health data and epidemiological information to better provide doctors with the necessary support to diagnose and treat patients more effectively to improve patient outcomes. Member States should put in place incentives to ensure that the data is completely interoperable to unlock the full potential of Europe's high quality healthcare services, while complying with Regulation (EU) 2016/679. 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 35**

# Proposal for a regulation Recital 46

Text proposed by the Commission

(46) Having information on how highrisk 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

#### Amendment

(46) Having information on how highrisk AI systems have been *designed and* 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

PE731.563v02-00 558/665 RR\1279290EN.docx

validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date. validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

#### Amendment 36

### Proposal for a regulation Recital 46a

Text proposed by the Commission

#### Amendment

(46a) Artificial intelligence should contribute to the European Green Deal and the green transition and be used by governments and businesses to benefit people and the planet. In this regard, the Commission and Member States should encourage the design, development, deployment and use of energy efficient and low carbon AI systems through the development of best practice procedures and the publication of guidelines and methodologies. In addition, the Commission should develop a procedure, methodology, minimum standards and scale, to be applied to all AI systems on a voluntary basis, to facilitate a multicriteria disclosure of information on the energy used in the training, retraining, fine tuning and execution of AI systems and a quantitative assessment of how the AI system affects climate change mitigation and adaption, including their carbon intensity.

#### Amendment 37

### 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

### 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. Users *and end recipients* should be able to

RR\1279290EN.docx 559/665 PE731.563v02-00

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.

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 38**

# Proposal for a regulation Recital 48

Text proposed by the Commission

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 inbuilt 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

High-risk AI systems should be (48)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 inbuilt 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. Appropriate human oversight and any subsequent intervention should not result in the intended function of the AI system being affected in a way that risks health, safety or fundamental rights, as applicable in the light of the intended purpose of the system.

**Amendment 39** 

Proposal for a regulation Recital 48 a (new)

PE731.563v02-00 560/665 RR\1279290EN.docx

#### Amendment

(48a) The recommendations regarding human oversight from the opinion of the Committee on the Environment, Public Health and Food Safety for the Committee on Legal Affairs with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL)) are to complement this Regulation.

#### Amendment 40

# 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 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 *and end recipients*.

### **Amendment 41**

# 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

#### Amendment

(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, *negative environmental* 

fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system. *implications*, or negatively affect the fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system.

#### **Amendment 42**

### 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, including the energy consumption and carbon intensity of the system and establish a robust postmarket 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. Where this overlaps with any relevant and applicable sectoral legislation, the relevant terminology should be appropriately harmonised to avoid any unnecessary fragmentation.

#### **Amendment 43**

Proposal for a regulation Recital 59 a (new)

Text proposed by the Commission

#### Amendment

(59a) Considering the specific nature and potential uses of AI systems which can be addressed to natural persons who are not users or operators, it is important to ensure the protection of certain rights,

PE731.563v02-00 562/665 RR\1279290EN.docx

notably regarding transparency and the provision of information, to end recipients such as patients of healthcare services, students, consumers, etc. The current legislation should aim at providing the appropriate type and degree of transparency as well as the provision of specific information to end recipients and establish a clear difference with users as it can increase the protection and usability of AI systems and components.

#### Amendment 44

# 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

(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons, the environment and climate change 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, the protection of the environment 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 45

# 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

### 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 *these* circumstances, the use of these

RR\1279290EN.docx 563/665 PE731.563v02-00

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.

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 a timely and accessible format paying particular attention to 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.

#### **Amendment 46**

# 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

# Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel *and effective* 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, *sustainable* 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, *with* 

PE731.563v02-00 564/665 RR\1279290EN.docx

regulatory oversight before these systems are placed on the market or otherwise put into service.

particular emphasis on the promotion of sustainable and green AI systems, under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

#### Amendment 47

# 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. 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

RR\1279290EN.docx 565/665 PE731.563v02-00

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.

expeditiously and in good faith to mitigate any high-risks to safety, *health*, *the environment* 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 48

Proposal for a regulation Recital 73 a (new)

Text proposed by the Commission

#### Amendment

(73a) In order to promote a more sustainable and greener innovation, the Commission and Member States should publish guidelines and methodologies for efficient algorithms that provide data and pre-trained models in view of a rationalisation of training activity. The development of best practice procedures would also support the identification and subsequent development of solutions to the most pressing environmental challenges of AI systems, including on the development of the green AI label.

### **Amendment 49**

# 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

#### 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, *the European Institute* 

PE731.563v02-00 566/665 RR\1279290EN.docx

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.

of Innovation and Technology, 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 50

# 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

In order to facilitate a smooth, (76)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, the establishment of an artificial intelligence sustainability taskforce for the sustainable development of artificial intelligence and the development towards a harmonised criteria for sustainable technical specifications, existing standards and best *practice* regarding the requirements established in this Regulation and to provide expert advice to and assisting the Commission on specific questions related to artificial intelligence to better address emerging cross-border challenges arising from rapid technological development.

#### Amendment 51

Proposal for a regulation Recital 76 a (new)

#### Amendment

(76a) To ensure a common and consistent approach regarding the deployment and implementation of AI systems in the various areas and sectors concerned and to exploit potential synergies and complementarities, the Board should cooperate closely with other relevant sectoral advisory groups established at Union level, such as boards, committees and expert groups, including organisations from the civil society such as NGOs, consumer associations, and industry representatives with competence in areas related to digital technologies or artificial intelligence, such as governance, exchange, access or use and re-use of data, including health data or environmental information, while avoiding duplication of work.

#### Amendment 52

# 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

#### 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 protecting

PE731.563v02-00 568/665 RR\1279290EN.docx

fundamental rights resulting from the use of their AI systems.

fundamental rights resulting from the use of their AI systems. Likewise, civil society organisations and other stakeholders should be enabled to provide input and lodge complaints if the protection of fundamental rights or public interest is at risk.

#### Amendment 53

# 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 accordance with the requirements of this Regulation *should* 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 take a risk-based approach to focus on the direct and indirect effects on environmental sustainability, energy efficiency and carbon intensity, 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 54**

RR\1279290EN.docx 569/665 PE731.563v02-00

# 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 to ensure the protection for the public interest, the health and safety of consumers and the protection of the environment for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

#### Amendment 55

Proposal for a regulation Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

#### Amendment

(4a) 'end recipient' means any natural or legal person, other than an operator, to whom the output of an AI system is intended or to whom that output is provided;

#### Amendment 56

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 or the failure or malfunctioning of which endangers the health and safety of persons or property or climate and environmental protection;

#### Amendment 57

Proposal for a regulation Article 3 – paragraph 1 – point 15

PE731.563v02-00 570/665 RR\1279290EN.docx

(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 *and end recipient* 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 58

Proposal for a regulation Article 3 – paragraph 1 – point 24 b (new)

Text proposed by the Commission

#### Amendment

(24b) "green AI label" means a label by which the less carbon intensive and most energy efficient AI systems are recognised and that promotes the techniques and procedures used for a better efficiency;

### **Amendment 59**

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 neurological* data;

#### **Amendment 60**

Proposal for a regulation Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting

Amendment

(a) the placing on the market, putting

RR\1279290EN.docx 571/665 PE731.563v02-00

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; into service or use of an AI system that deploys subliminal, *psychological* 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 *economic*, physical or psychological harm;

### Justification

Discriminatory AI driven price optimisation strategies should not be permitted. For example: insurance firms targeting price increases at consumers who are perceived by AI systems as less likely to switch providers

#### **Amendment 61**

# 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 *including addiction, bereavement or distress*, 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 *economic*, physical or psychological harm;

### Justification

The protection of vulnerable citizens should include those suffering from temporary vulnerabilities including addiction or bereavement to ensure protection from the use of AI driven persuasion profiling used in dating and gambling websites for example.

#### Amendment 62

Proposal for a regulation Article 7 – paragraph 1 – point a

PE731.563v02-00 572/665 RR\1279290EN.docx

# (a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;

#### Amendment

(a) the AI systems are intended to be used in any of the areas listed in points 1 to 9 of Annex III;

#### Amendment 63

# 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 and safety, or a risk of adverse impact on *climate change mitigation and adaptation, the environment and* 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 64**

# 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 *the climate, the environment or* 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 65**

Proposal for a regulation Article 7 – paragraph 2 – point c

RR\1279290EN.docx 573/665 PE731.563v02-00

(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 *climate, the environment and* 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 66**

# 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, *the environment and biodiversity*;

#### Amendment 67

# 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, *including end recipients*, are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to optout from that outcome:

### **Amendment 68**

Proposal for a regulation Article 7 – paragraph 2 – point f

PE731.563v02-00 574/665 RR\1279290EN.docx

(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;

#### 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, *environmental* or social circumstances, or age;

#### Amendment 69

# 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 adverse impact on the climate, the environment, on biodiversity or negatively affecting the ability to achieve greenhouse gas reduction targets or the health or safety of persons shall not be considered as easily reversible;

#### Amendment 70

# Proposal for a regulation Article 9 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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

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 *and to the end recipient*.

#### Amendment 71

# 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, 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, *including end recipients*. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

#### Amendment 72

# 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 take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, *environmental*, behavioural or functional setting within which the high-risk AI system is intended to be used.

#### Amendment 73

# 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

#### Amendment

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in

PE731.563v02-00 576/665 RR\1279290EN.docx

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.

relation to the high-risk AI systems *and to* ensure algorithmic non-discrimination, 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 privacypreserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

## **Amendment 74**

# Proposal for a regulation Article 13 – title

Text proposed by the Commission

Transparency and provision of information to users

# Amendment 75

# 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

Transparency and provision of information to users *and end recipients* 

#### 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 *and end recipients* 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, *end recipient* and of the provider set out in Chapter 3 of this Title.

#### Amendment 76

# 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 is relevant, accessible and comprehensible to users, including in relation to possible risks to fundamental rights and discrimination.

#### Amendment 77

# 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 misuse, which may lead to risks to the health and safety or *the environment or* fundamental rights;

#### Amendment 78

Proposal for a regulation Article 13 – paragraph 3 a (new)

Text proposed by the Commission

# Amendment

3a. High-risk AI systems shall be designed, developed and used in such a way to ensure that the outputs are sufficiently transparent, relevant, accessible and comprehensible to the end recipients, in accordance with the intended purpose.

PE731.563v02-00 578/665 RR\1279290EN.docx

#### Amendment 79

# 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 *disinformation* as well as the risks to health, safety, the climate and environment 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 80

# 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 the system through a "stop" button or a similar procedure provided that the intended function of the AI system is not affected in a way that risks health, safety or fundamental rights.

#### **Amendment 81**

# 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 *concise and clear* documentation and instructions of use, *including in relation to possible risks to* 

# fundamental rights and discrimination.

#### **Amendment 82**

# 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 83

# 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

# Amendment

2. For high-risk AI systems referred to in points 2 to 9 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

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, to the environment and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified

PE731.563v02-00 580/665 RR\1279290EN.docx

among notified bodies.

bodies.

#### Amendment 84

# 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, *especially in the healthcare sector*, 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 85**

Proposal for a regulation Article 52 – paragraph 3 a (new)

Text proposed by the Commission

# Amendment

3 a. Recipients of an AI system in the domain of healthcare shall be informed of their interaction with an AI system.

# **Amendment 86**

Proposal for a regulation Article 52 – paragraph 3 b (new)

Text proposed by the Commission

#### Amendment

3b. Public and administrative authorities which adopt decisions with the assistance of AI systems shall provide a clear and intelligible explanation. The

RR\1279290EN.docx 581/665 PE731.563v02-00

explanation shall be accessible for persons with disabilities and other vulnerable groups.

#### **Amendment 87**

# 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 *climate mitigation, the environment,* health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.

# **Amendment 88**

# 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 *or the environment* as a result from the experimentation taking place in the sandbox.

# **Amendment 89**

# Proposal for a regulation Article 54 – paragraph 1 – point a – point ii

Text proposed by the Commission

(ii) public safety and public health,

Amendment

(ii) public safety and public health,

PE731.563v02-00 582/665 RR\1279290EN.docx

including disease prevention, control and treatment;

including disease detection, diagnosis, prevention, control and treatment, and the health challenges in relation to the interlinkage between human and animal health, in particular zoonotic diseases;

#### **Amendment 90**

# 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, protection of biodiversity, pollution as well as climate change mitigation and adaptation;

#### **Amendment 91**

Proposal for a regulation Article 54 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) the principle of data minimisation shall be upheld, meaning that the data acquisition and processing shall be kept to what is strictly necessary for the purpose of the artificial intelligence application;

#### Amendment 92

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 Amendment

(b) coordinate and contribute to guidance and analysis by the Commission and the national supervisory authorities as well as advisory and expert groups, including organisations from the civil society such as NGOs, consumer associations, and industry representatives

RR\1279290EN.docx 583/665 PE731.563v02-00

Regulation;

and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation;

#### Amendment 93

# 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. Other national authorities *including those which are members of relevant advisory and expert groups at Union level*, may be invited to the meetings, where the issues discussed are of relevance for them.

# **Amendment 94**

# 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, *ethicists* and observers to attend its meetings and may hold exchanges with interested third parties *including* organisations from the civil society such as NGOs, consumer associations, human rights groups and intergovernmental organisations and industry representatives to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other *relevant* Union bodies, offices, agencies and *expert* advisory groups.

# **Amendment 95**

PE731.563v02-00 584/665 RR\1279290EN.docx

# Proposal for a regulation Article 58 – paragraph 1 – point a

Text proposed by the Commission

(a) collect and share expertise and best practices among Member States;

# Amendment

(a) collect and share *technical and regulatory* expertise and best practices among Member States;

# Justification

It should be specified that the technical as well as from the regulatory views are considered.

# **Amendment 96**

Proposal for a regulation Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) ensure that there is a common and consistent approach among the different advisory and expert groups established at Union level on matters covered by this Regulation or related to AI systems.

# **Amendment 97**

# 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. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation and horizontal Union legislation. National competent authorities shall be organised so as to safeguard the objectivity, consistency and impartiality of their activities and tasks to avoid any conflicts of interest.

RR\1279290EN.docx 585/665 PE731.563v02-00

#### **Amendment 98**

# 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 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 protection and data computing, fundamental rights, health and safety risks, environmental risks and knowledge of existing standards and legal requirements.

# **Amendment 99**

# Proposal for a regulation Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

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 *health*, *safety*, fundamental rights *and the environment* to the market surveillance authorities of the Member States where that incident or breach occurred.

# **Amendment 100**

Proposal for a regulation Article 65 – paragraph 1

PE731.563v02-00 586/665 RR\1279290EN.docx

# 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, *the protection of consumers and the environment or where* the protection of fundamental rights of persons are concerned.

#### Amendment 101

# 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

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 environment, 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 102

# 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

# Amendment

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.

up of codes of conduct intended to foster the voluntary application to AI systems of requirements related to a European code for data centre energy efficiency that shall contain key indicators related to environmental sustainability, resource usage, energy efficiency and carbon intensity, the proportion of energy generated from renewable energy sources and reuse of any heat or waste. This could be extended to encourage the accessibility for persons with a disability, stakeholders' participation in the design and development of the AI systems as well as the diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives. In order to facilitate the voluntary application of environmental assessments, the Commission shall develop, by means of an implementing act, a procedure, methodology, minimum standards and scale to facilitate the disclosure of information on the energy used in the training and execution of AI systems and their carbon intensity to promote the development of energy efficient and low carbon AI systems, which shall be applicable to all AI systems on a voluntary basis. Those AI systems voluntarily participating shall include this information in the technical documentation referred to in article 11.

**Amendment 103** 

Proposal for a regulation Article 84 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. 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 environmental impact and effectiveness of this Regulation with

regards to energy use or other environmental impact of AI systems. By January 2050, the Commission shall present a proposal to regulate the energy efficiency to ensure the full decarbonisation of AI technologies.

# Amendment 104

# Proposal for a regulation Annex I – point a

Text proposed by the Commission

(a) Machine learning approaches, including supervised, unsupervised *and* reinforcement learning, using a wide variety of methods including deep learning;

#### Amendment

(a) Machine learning approaches, including supervised, unsupervised, reinforcement learning *and computational scientific discovery*, using a wide variety of methods including deep learning;

# **Amendment 105**

# 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, *including healthcare service and health literacy*, as well as to grant, reduce, revoke, or reclaim such benefits and services;

# **Amendment 106**

Proposal for a regulation Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

#### Amendment

8a. Health, health care, long-term care and health insurance:

- (a) AI systems not covered by Regulation (EU) 2017/745 intended to be used in the health, health care and long-term care sectors that have indirect and direct effects on health or that use sensitive health data.
- (b) Artificial intelligence administrative and management systems used by healthcare professionals in hospitals and other healthcare settings and by health insurance companies that process sensitive data of people's health.

# Justification

The proposal assumes that all AI applications used in the context of health are covered by Regulation (EU) 2017/745. However, this Regulation only covers medical devices and software with an intended medical purpose, such as treatment of patients. This excludes health related AI applications (for example, apps to track medication) and administrative AI systems used by doctors in a hospital or other healthcare setting that still present new challenges and possible risks to people, because of their effects on health or the use of sensitive health data and life choices.

# **Amendment 107**

Proposal for a regulation Annex IV – paragraph 1 – point 1 – point g

Text proposed by the Commission

Amendment

- (g) instructions of use for the user and, where applicable installation instructions;
- (g) clear and concise instructions of use for the user and the end recipient, including in relation to possible risks to fundamental rights and discrimination and, where applicable installation instructions;

# **Amendment 108**

Proposal for a regulation Annex IV – paragraph 1 – point 2 – point g a (new)

Text proposed by the Commission

Amendment

(ga) the computational complexity of the system and its software components,

PE731.563v02-00 590/665 RR\1279290EN.docx

its data use, including the validation and testing of systems.

# Amendment 109

# Proposal for a regulation Annex IV – paragraph 1 – point 3

Text proposed by the Commission

Detailed information about the 3. 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 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;

#### Amendment

3. Detailed information and fully accessible 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 the environment, health and safety, fundamental rights and discrimination in view of the intended purpose 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;

RR\1279290EN.docx 591/665 PE731.563v02-00

# PROCEDURE - COMMITTEE ASKED FOR OPINION

Title	Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts
References	COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)
Committees responsible Date announced in plenary	IMCO LIBE 7.6.2021 7.6.2021
Opinion by Date announced in plenary	ENVI 7.6.2021
Rapporteur for the opinion Date appointed	Susana Solís Pérez 15.9.2021
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021
Discussed in committee	13.1.2022
Date adopted	15.3.2022
Result of final vote	+: 67 -: 4 0: 15
Members present for the final vote	Mathilde Androuët, Nikos Androulakis, Bartosz Arłukowicz, Margrete Auken, Simona Baldassarre, Marek Paweł Balt, Traian Băsescu, Aurélia Beigneux, Monika Beňová, Hildegard Bentele, Sergio Berlato, Alexander Bernhuber, Malin Björk, Simona Bonafè, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Nathalie Colin-Oesterlé, Esther de Lange, Christian Doleschal, Marco Dreosto, Bas Eickhout, Cyrus Engerer, Cornelia Ernst, Eleonora Evi, Agnès Evren, Pietro Fiocchi, Raffaele Fitto, Malte Gallée, Andreas Glück, Catherine Griset, Jytte Guteland, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Pär Holmgren, Jan Huitema, Yannick Jadot, Adam Jarubas, Petros Kokkalis, Athanasios Konstantinou, Ewa Kopacz, Joanna Kopcińska, Peter Liese, Sylvia Limmer, Javi López, César Luena, Fulvio Martusciello, Liudas Mažylis, Joëlle Mélin, Tilly Metz, Silvia Modig, Dolors Montserrat, Alessandra Moretti, Dan-Ştefan Motreanu, Ville Niinistö, Ljudmila Novak, Grace O'Sullivan, Jutta Paulus, Stanislav Polčák, Jessica Polfjärd, Nicola Procaccini, Luisa Regimenti, Frédérique Ries, María Soraya Rodríguez Ramos, Sándor Rónai, Rob Rooken, Silvia Sardone, Christine Schneider, Günther Sidl, Ivan Vilibor Sinčić, Linea Søgaard-Lidell, Maria Spyraki, Nils Torvalds, Edina Tóth, Véronique Trillet-Lenoir, Petar Vitanov, Alexandr Vondra, Mick Wallace, Emma Wiesner, Michal Wiezik, Tiemo Wölken, Anna Zalewska
Substitutes present for the final vote	Maria Arena, Marlene Mortler, Susana Solís Pérez

PE731.563v02-00 592/665 RR\1279290EN.docx

# FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

67	+
NI	Edina Tóth
ЕРР	Bartosz Arłukowicz, Traian Băsescu, Hildegard Bentele, Alexander Bernhuber, Nathalie Colin-Oesterlé, Christian Doleschal, Agnès Evren, Adam Jarubas, Ewa Kopacz, Esther de Lange, Peter Liese, Fulvio Martusciello, Liudas Mažylis, Dolors Montserrat, Marlene Mortler, Dan-Ştefan Motreanu, Ljudmila Novak, Stanislav Polčák, Jessica Polfjärd, Luisa Regimenti, Christine Schneider, Maria Spyraki
Renew	Pascal Canfin, Andreas Glück, Martin Hojsík, Jan Huitema, Frédérique Ries, María Soraya Rodríguez Ramos, Susana Solís Pérez, Linea Søgaard-Lidell, Nils Torvalds, Véronique Trillet-Lenoir, Emma Wiesner, Michal Wiezik
S&D	Nikos Androulakis, Maria Arena, Marek Paweł Balt, Monika Beňová, Simona Bonafè, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Cyrus Engerer, Jytte Guteland, Javi López, César Luena, Alessandra Moretti, Sándor Rónai, Günther Sidl, Tiemo Wölken
The Left	Malin Björk, Anja Hazekamp, Petros Kokkalis, Silvia Modig, Mick Wallace
Verts/ALE	Margrete Auken, Bas Eickhout, Eleonora Evi, Malte Gallée, Pär Holmgren, Yannick Jadot, Tilly Metz, Ville Niinistö, Grace O'Sullivan, Jutta Paulus

4	-
ID	Simona Baldassarre, Marco Dreosto, Sylvia Limmer, Silvia Sardone

15	0
ECR	Sergio Berlato, Pietro Fiocchi, Raffaele Fitto, Joanna Kopcińska, Nicola Procaccini, Rob Rooken, Alexandr Vondra, Anna Zalewska
ID	Mathilde Androuët, Aurélia Beigneux, Catherine Griset, Teuvo Hakkarainen, Joëlle Mélin
NI	Athanasios Konstantinou, Ivan Vilibor Sinčić

Key to symbols: + : in favour - : against 0 : abstention

RR\1279290EN.docx 593/665 PE731.563v02-00

# OPINION OF THE COMMITTEE ON TRANSPORT AND TOURISM

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

on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts

(COM(2021)0206 - C9-0146/2021 - 2021/0106(COD))

Rapporteur for opinion: Josianne Cutajar

# SHORT JUSTIFICATION

The Rapporteur supports the development of an EU legislative framework on Artificial Intelligence, a necessary step to ensure the Union becomes leader in the field, all while upholding our European values. The horizontal risk-based approach of the Artificial Intelligence Act will create a system in which rules will apply exclusively to applications of AI systems where threats may occur. This selective approach will allow the Union to continue developing its AI sector without hindering technological progress and digital transformation.

Transport is a sector posed to benefit greatly from the integration of AI systems in its every day operations and logistics. The application of AI systems can help achieve the EU's safety, environmental and, in some instances, societal objectives for the sector. The Union must therefore aim at removing those existing barriers that hinder development and investment, first among all, legal fragmentation and uncertainty, which hurts business and customers.

The key elements of the Rapporteur's report are the following:

Ensuring the AI Act does not overlap with sectoral legislation by imposing
double/conflicting obligations on transport actors;
Promoting the development of, and upholding, international standards, that are
particularly important for the transport sector;
Fostering Research and Innovation to ensure the EU's transport sector develops its
own know-how in the implementation of AI, while upholding the highest ethical
standards.

The general approach to the opinion by the Rapporteur has been to give a voice to the transport sector on the AI Act. For this reason, amendments had to be carefully drafted within the scope of the TRAN Committee, a complicated task when dealing with harmonized legislation. Still, the Rapporteur believes that in instances where horizontal provisions clearly affect transport, the TRAN Committee should have a say. In addition, some amendments have been included to clarify the key messages of the Commission's report, such as in the case of the definition of AI systems and High-Risk, which are both essential for transport.

Following the consultation and research phase for this work, three clear issues emerged from a TRAN perspective. First, each segment of transport already presents, in different degrees and forms, sectoral legislation, provisions or initiatives to ensure the highest level of safety when it comes to AI system integration. Aviation, road, rail and maritime, all require measures specifically tailored to the sector to ensure the successful management of operations and services, while upholding the highest level of security. Harmonized legislation might fall short of the required measures to guarantee the aforementioned safety in the sector. For this reason, it was paramount to stress in the AI Act the need for sectoral legislation to be respected and prevail, in some instances, over harmonized rules. This was indeed the intention of the Commission as clear from Annex II, Part B. Yet, the text required further detail.

Secondly, due to the international nature of transport, a second key element that emerged from assessment is that international procedures are already in motion to develop global norms and guidelines for the safety of AI systems for each sector. It would be preferable therefore, that such global standards are respected and integrated in EU law and standards. Generally speaking, EU standards are developed through formal agreements between the European Standardization Organizations (ESOs) and International Standardization Organizations, which allows them in practice to work together. Nonetheless, in the interest of preserving the competitiveness of the EU's transport sector vis-a-vis other regions, the language and provisions in the AI Act had to be strengthened to ensure provisions on AI for transport are respectful of the international norms and standards.

Lastly, Research and Development is the motor for the digitalization of each sector, let alone transport. New harmonized rules on AI must not impede research where such research is limited to controlled environments and the studied AI System is not placed onto the market. For this reason, language is added to clarify the scope in this regard. It must be noted, that the Commission proposal presents measures in support of innovation through specific articles on sandboxes and small-scale providers. Here, however, the Rapporteur amends to ensure Small and Medium Enterprises (SMEs) are able to benefit from such provisions.

Further minor amendments by the Rapporteur cover transparency of algorithms for transport work (simply reflecting Commission's language in Annex III), an understanding of Human Oversight in the context of transport, and clarification on errors in data sets.

# **AMENDMENTS**

The Committee on Transport and Tourism calls on the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs, as the committees responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation Recital 1

# Text proposed by the Commission

The purpose of this Regulation is to (1) 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 AIbased 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

The purpose of this Regulation is to (1) 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, fundamental rights and the environment, 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 2

# 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

# Amendment

A Union legal framework laying (5) 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 environment, 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

PE731.563v02-00 596/665 RR\1279290EN.docx

secure, trustworthy and ethical artificial intelligence, as stated by the European Council<sup>33</sup>, and it ensures the protection of ethical principles, as specifically requested by the European Parliament<sup>34</sup>.

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

development of secure, trustworthy and

specifically requested by the European

protection of ethical principles, as

Parliament<sup>34</sup>.

ethical artificial intelligence, as stated by the European Council<sup>33</sup>, and it ensures the

# **Amendment 3**

# Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

#### Amendment

Union legislation on artificial (5a)intelligence should contribute to the dual green and digital transition. The artificial intelligence can contribute positively to the green transition but also has significant environmental impacts due to the critical raw material required to design and build its infrastructure and microprocessors and the energy used for its development, training, tuning and use. Development and use of AI should therefore be compatible with sustainable environmental resources at all stages of the lifecycle of AI systems. Also, unnecessary data acquisition and processing should be avoided. Moreover, Union legislation on artificial intelligence should be accompanied by actions aimed at addressing the main barriers hindering the digital transformation of the economy. Such measures should focus on education, upskilling and reskilling of

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

<sup>&</sup>lt;sup>34</sup> 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).

<sup>&</sup>lt;sup>34</sup> 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).

workers, fostering investment in research and innovation, and boosting security in the digital sphere in line with initiatives aimed at achieving the targets of the Digital Decade. Digital transformation should occur in a harmonized manner across regions, paying particular attention to less digitally developed areas of the Union.

#### Amendment 4

Proposal for a regulation Recital 5 b (new)

Text proposed by the Commission

#### Amendment

(5b)Harmonised Union legislation on artificial intelligence can contribute to create legal certainty and coherence across the Union. However, due to risks associated with passenger and goods transport, the sector has been carefully monitored and regulated to avoid incidents and loss of life. The Union legal framework for transport presents sectoral legislation for the aviation, road, rail and maritime transport. With the progressive integration of AI systems in the sector, new challenges could emerge in risk management. This Regulation should only apply to high risk applications in the transport sector in so far as that they are not already covered by sectoral legislation and where they could have a harmful impact on the environment or health, safety and fundamental rights of persons. Double regulation should therefore be avoided.

**Amendment 5** 

Proposal for a regulation Recital 5 c (new)

PE731.563v02-00 598/665 RR\1279290EN.docx

#### Amendment

The Union aviation sector, for (5c)example, through the work of the European Aviation Safety Agency (EASA) and its stakeholders, is gradually developing its own guidance material and rules on the application and security management of AI systems in aviation. In the EASA's roadmap for AI, AI systems with application to aviation are categorised in three distinct levels, from assistance to human, to human-machine cooperation, to full machine automation. A sector-specific oversight on AI systems laying out rules for the highest-level of safety for aviation while preserving the global competitiveness of Union businesses is needed.

#### Amendment 6

# 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 standalone 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

# Amendment

The notion of AI system should be (6) 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, and possibly also the hardware. <sup>1a</sup> In particular, for the purpose of this Regulation, AI systems should be intended as having the ability, on the basis of machine- and/or human-based data and inputs, to infer the way to achieve a given set of human-defined objectives through learning, reasoning or modelling and generate specific outputs in the form of content for generative AI systems, as well as predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems

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 standalone 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.

 1a https://digitalstrategy.ec.europa.eu/en/library/definition -artificial-intelligence-main-capabilitiesand-scientific-disciplines

#### Amendment 7

Proposal for a regulation Recital 8 a (new)

Text proposed by the Commission

# Amendment

(8a) The use of biometrics and high technologies in transport and tourism may vastly benefit user experience and overall safety and security. This Regulation should accompany these developments by setting the highest level of protection, in particular when use of biometrics data is involved, in line with the data protection framework of the Union, while fostering research and investment for the development and deployment of AI systems that can positively contribute to society.

### **Amendment 8**

PE731.563v02-00 600/665 RR\1279290EN.docx

# Proposal for a regulation Recital 12 a (new)

Text proposed by the Commission

#### Amendment

(12a) This Regulation should support research and innovation for the application of AI systems in the transport and tourism sectors while ensuring a high level of protection of public interests, such as health, safety, fundamental rights, the environment and democracy. For this reason, this Regulation should exclude from its scope applications of AI systems developed, applied and assessed in a controlled testing environment, for the sole purpose of evaluating their use and functionality. As regards product oriented research activity by providers, the provisions of this Regulation should apply insofar as such research leads to or entails placing an AI system on the market or putting it into service. All forms of research and development should be conducted in compliance with the highest ethical standards for scientific research.

# **Amendment 9**

# 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 and the environment, 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. This is of particular importance in the transport sector in order to ensure the highest level of interoperability among

RR\1279290EN.docx 601/665 PE731.563v02-00

transport vehicles, infrastructure and intelligent systems and to guarantee safety and security. The Union and its standards organisations should participate actively in the development of global standards for the different transport modes with a view to align them as much as possible with any applicable European standards and to ensure that they are in compliance with Union law. Regular reviews of this Regulation should take into account updated standards for the transport sector.

#### Amendment 10

Proposal for a regulation Recital 17 a (new)

Text proposed by the Commission

Amendment

(17a) The use of AI in work can be beneficial to both the management and operations of an enterprise, supporting workers in their tasks and improving safety at the workplace. Still, AI systems applied to the management of workers, in particular by digital labour platforms, including in the field of transport, can entail a number of risks such as unjust/unnecessary social scoring, rooted in biased data sets or intrusive surveillance practice which can lead to violation of workers' and fundamental rights. This Regulation should therefore aim at protecting the rights of transport workers managed with the assistance of AI systems, including those working via digital labour platforms and promote transparency, fairness and accountability in algorithmic management, to ensure that workers have a broad understanding of how algorithms work, which personal data is issued and how their behaviour affects decisions taken by the automated system.

#### Amendment 11

# Proposal for a regulation Recital 17 b (new)

Text proposed by the Commission

#### Amendment

(17b) In addition, users and individuals should 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 them, or similarly significantly affects them.

# **Amendment 12**

# Proposal for a regulation Recital 27

Text proposed by the Commission

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

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 the environment and such limitation minimises any potential restriction to international trade, if any.

# **Amendment 13**

Proposal for a regulation Recital 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 Council<sup>39</sup>, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>40</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>41</sup>, Directive 2014/90/EU of the European Parliament and of the Council<sup>42</sup>, Directive (EU) 2016/797 of the European Parliament and of the Council<sup>43</sup>, Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>44</sup>, Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>45</sup>, and Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>46</sup>, 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 Council<sup>39</sup>, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>40</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>41</sup>, Directive 2014/90/EU of the European Parliament and of the Council<sup>42</sup>, Directive (EU) 2016/797 of the European Parliament and of the Council<sup>43</sup>, Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>44</sup>, Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>45</sup>, and Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>46</sup>, it is appropriate, if required, 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 overlapping 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. Transport sectoral legislation should prevail over this Regulation and it should be ensured that no conflicting overlap exists between this Regulation and other current and upcoming legal acts (i.e. Data Act, ITS Review) to avoid duplication of obligations on providers and manufacturers, which would cause legal uncertainty for business and slow down the uptake of new technologies in the market. This Regulation should also provide for an efficient review mechanism in order to take into account future technological developments and to ensure

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fair, proportionate and targeted implementation. In order to avoid substantial legal uncertainty, and to ensure that this Regulation applies to all sectors concerned by it without undue delays, those acts should be amended to integrate the provisions of this Regulation no later than 24 months after its entry into force.

<sup>&</sup>lt;sup>39</sup> 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).

<sup>&</sup>lt;sup>40</sup> 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).

<sup>&</sup>lt;sup>41</sup> 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).

<sup>&</sup>lt;sup>42</sup> 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).

<sup>&</sup>lt;sup>43</sup> 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).

<sup>&</sup>lt;sup>44</sup> 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,

<sup>&</sup>lt;sup>39</sup> 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).

<sup>&</sup>lt;sup>40</sup> 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).

<sup>&</sup>lt;sup>41</sup> 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).

<sup>&</sup>lt;sup>42</sup> 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).

<sup>&</sup>lt;sup>43</sup> 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).

<sup>&</sup>lt;sup>44</sup> 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).

<sup>45</sup> 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).

<sup>46</sup> 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).

14.6.2018, p. 1).

<sup>45</sup> 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).

<sup>46</sup> 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).

# **Amendment 14**

Proposal for a regulation Recital 32

# Text proposed by the Commission

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

As regards stand-alone AI systems, (32)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 or the environment, 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 15**

# 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

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. Some examples of critical infrastructure management systems for road covered by Annex III should include traffic management control systems, intelligent transport systems and ICT infrastructure connected transport.

# **Amendment 16**

# Proposal for a regulation Recital 37

Text proposed by the Commission

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-

# 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, gender, 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-

PE731.563v02-00 608/665 RR\1279290EN.docx

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 highrisk since they make decisions in very critical situations for the life and health of persons and their property.

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 highrisk since they make decisions in very critical situations for the life and health of persons and their property.

# **Amendment 17**

# Proposal for a regulation Recital 43

Text proposed by the Commission

(43) Requirements should apply to highrisk 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 18**

Proposal for a regulation Recital 44

#### Amendment

(43) Requirements should apply to highrisk 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 *and the environment*, 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.

# 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 *shouldbe* 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 highrisk AI systems.

#### Amendment

High data quality is essential for the (44)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, up to date and, to the best extent possible free of errors and as complete as possible in view of the intended purpose of the system and to ensure the highest level of security. 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 ensure that databases contain adequate data on groups which are more vulnerable to discriminatory effects posed by AI, such as people with disabilities, and **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, update, and correction in relation to high-risk AI systems.

# **Amendment 19**

# 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, in particular when applied to digital labour platforms managing the activities of transport workers. Users should be able to interpret the system output and use it appropriately. Transparency, fairness, accountability and explanability of AI systems can also be a beneficial factor for their uptake by consumers in the market. 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 20**

Proposal for a regulation Recital 47 a (new)

Text proposed by the Commission

# Amendment

(47a) Based on previous experience, it is particularly important to ensure clear requirements and guidelines for interoperability between AI systems both within and amongst different economic sectors, contributing to foster innovation and providing favourable conditions for small and medium enterprises (SMEs).

# **Amendment 21**

Proposal for a regulation Recital 48

RR\1279290EN.docx 611/665 PE731.563v02-00

# Text proposed by the Commission

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 inbuilt 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 can oversee their functioning, unless there is clear evidence that it doesn't add value and could even be detrimental to the protection of health, safety and fundamental rights. 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. With regards to the transport sector, the AI system applications should respect the sector-specific legislation in place. When physical security is at stake, Union standards, and where applicable international standards, should determine in which case the possibility for a human operator to take back control should take prevalence over AI system's decision.

#### **Amendment 22**

# 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,

PE731.563v02-00 612/665 RR\1279290EN.docx

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 accessing the data of providers of high risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

#### Amendment 23

# 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, should be made 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.

#### Amendment 24

# 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 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.

#### Amendment 25

# Proposal for a regulation Recital 71

Text proposed by the Commission

Artificial intelligence is a rapidly (71)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

Artificial intelligence is a rapidly (71)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 and make such regulatory sandboxes widely available throughout the Union, in order 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. It is especially important to ensure that SMEs and startups can easily access these sandboxes, are actively involved and participate in the development and testing of innovative AI systems, in order to be able to contribute with their knowhow and experience. Their participation should be supported and

PE731.563v02-00 614/665 RR\1279290EN.docx

#### Amendment 26

# Proposal for a regulation Recital 72

Text proposed by the Commission

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 expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the

#### 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 and startups, as well as to contribute to achieving the targets on AI as set in the Policy Programme "Path to the Digital Decade". 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

RR\1279290EN.docx 615/665 PE731.563v02-00

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.

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 27

# Proposal for a regulation Recital 73

Text proposed by the Commission

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

In order to promote and protect innovation, it is important that the interests of SMEs 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 should 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 28**

Proposal for a regulation Recital 76

PE731.563v02-00 616/665 RR\1279290EN.docx

# 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

In order to facilitate a smooth. (76)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. In order to ensure a common and consistent approach to the development of AI and ensure good cooperation and exchange of views, the Board should regularly consult other EU institutions, as well as all sector-specific relevant stakeholders.

#### Amendment 29

Proposal for a regulation Recital 77 a (new)

Text proposed by the Commission

# Amendment

(77a) To encourage knowledge sharing from best practices, the Commission should organise regular consultative meetings for knowhow exchange between different Member States' national authorities responsible for notification policy.

#### Amendment 30

Proposal for a regulation Article 1 – paragraph 1 – point e

## Text proposed by the Commission

#### Amendment

rules on market monitoring and (e) surveillance.

rules on market monitoring, market (e) surveillance, governance.

#### Amendment 31

Proposal for a regulation Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

provision to foster and support research and development for innovation.

#### **Amendment 32**

Proposal for a regulation Article 2 – paragraph 2 – introductory part

Text proposed by the Commission

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

For AI systems classified as highrisk 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:

#### Amendment 33

Proposal for a regulation Article 2 – paragraph 2 – point a

Text proposed by the Commission

Amendment

*Regulation (EC) 300/2008;* (a)

deleted

**Amendment 34** 

Proposal for a regulation Article 2 – paragraph 2 – point b

RR\1279290EN.docx PE731.563v02-00 618/665

Amendment Text proposed by the Commission *Regulation (EU) No 167/2013;* deleted **(b)** Amendment 35 Proposal for a regulation Article 2 – paragraph 2 – point c Text proposed by the Commission Amendment *Regulation (EU) No 168/2013;* deleted (c) **Amendment 36** Proposal for a regulation Article 2 - paragraph 2 - point d Amendment Text proposed by the Commission Directive 2014/90/EU; deleted (d) Amendment 37 Proposal for a regulation Article 2 – paragraph 2 – point e Amendment Text proposed by the Commission *Directive (EU) 2016/797;* deleted (e) **Amendment 38** Proposal for a regulation Article 2 – paragraph 2 – point f Text proposed by the Commission Amendment **(f)** *Regulation (EU) 2018/858;* deleted

RR\1279290EN.docx 619/665 PE731.563v02-00

**Amendment 39** 

Proposal for a regulation Article 2 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) Regulation (EU) 2018/1139;

deleted

**Amendment 40** 

Proposal for a regulation Article 2 – paragraph 2 – point h

Text proposed by the Commission

Amendment

(h) Regulation (EU) 2019/2144.

deleted

**Amendment 41** 

Proposal for a regulation Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. This Regulation shall not apply to AI systems, including their output, developed and put into service for the sole purpose of research and development.

**Amendment 42** 

Proposal for a regulation Article 2 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5b. 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 require placing an AI system on the market or putting it into service and is in full respect of approved scientific ethical standards.

**Amendment 43** 

PE731.563v02-00 620/665 RR\1279290EN.docx

# Proposal for a regulation Article 2 – paragraph 5 c (new)

Text proposed by the Commission

#### Amendment

5c. 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, Regulation (EU) 2018/1725, Directive 2002/57/EC and Directive (EU) 2016/680.

#### **Amendment 44**

# 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 humanbased 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;

#### **Amendment 45**

# 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;

#### **Amendment 46**

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 legislation listed in Annex II;

#### Amendment 47

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;

#### **Amendment 48**

Proposal for a regulation Article 3 – paragraph 1 – point 14

PE731.563v02-00 622/665 RR\1279290EN.docx

# 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 the failure or malfunctioning of which endangers the health and safety of persons or property;

#### **Amendment 49**

# 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, *disability*, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;

#### Amendment 50

# 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 *or malfunctioning of an AI* system that directly or indirectly leads, might have led or might lead to any of the following:

#### **Amendment 51**

Proposal for a regulation Article 3 – paragraph 1 – point 44 a (new) Text proposed by the Commission

Amendment

(44a) 'personal data' means data as defined in point (1) of Article 4 of Regulation (EU)2016/679;

#### **Amendment 52**

Proposal for a regulation Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44b) 'non-personal data' means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;

#### Amendment 53

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 that are similar to the techniques and approaches listed therein

## **Amendment 54**

Proposal for a regulation Article 6 – paragraph 1 – introductory part

*Text proposed by the Commission* 

Amendment

1. *Irrespective of whether* an AI

1. An AI system *that is itself a* 

PE731.563v02-00 624/665 RR\1279290EN.docx

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: product covered by the Union harmonisation legislation listed in Annex II shall be considered as high risk if 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 above mentioned legislation.

#### **Amendment 55**

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

2. An AI system intended to be used as a safety component of a product covered by the legislation referred to in paragraph I shall be considered as high risk if 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 abovementioned legislation. This provision shall apply irrespective of whether the AI system is placed on the market or put into service independently from the product.

#### **Amendment 56**

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

3. AI systems referred to in Annex III shall be considered high-risk.

#### Amendment 57

# Proposal for a regulation Article 6 – paragraph 2 a (new)

Text proposed by the Commission

#### Amendment

2a. The classification as high-risk as a consequence of Article 6(1) 6(2) and 6(3) 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.

#### Amendment 58

# 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 *or* safety, or a risk of adverse impact on fundamental rights *or the environment*, 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 59**

# 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

#### 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* that is equivalent to or greater than the risk of

PE731.563v02-00 626/665 RR\1279290EN.docx

systems already referred to in Annex III, the Commission shall take into account the following criteria: harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

#### Amendment 60

# 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 *or on the environment* 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 61

# 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 the environment*;

## **Amendment 62**

# 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

## Amendment

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an

RR\1279290EN.docx 627/665 PE731.563v02-00

impact on the health or safety of persons shall not be considered as easily reversible;

adverse impact on the health or safety of persons, or on the environment shall not be considered as easily reversible;

#### Amendment 63

# 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 sectoral legislation where applicable, harmonised standards and common specifications.

#### Amendment 64

# 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 that might cause harm or damage to the environment or to the health, safety and fundamental rights of persons in view of the intended purpose of or misuse of the high-risk AI system.

#### **Amendment 65**

# 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 other possibly arising risks based on the analysis of data gathered from the post-market monitoring system;

PE731.563v02-00 628/665 RR\1279290EN.docx

#### **Amendment 66**

# Proposal for a regulation Article 9 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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

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, *subject to terms, conditions as made available by the provider, and contractual and license restrictions*. Those residual risks shall be communicated to the user.

#### Amendment 67

# 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, where applicable.

#### **Amendment 68**

# 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, environment and safety or the* 

*fundamental rights of persons*, and how those gaps and shortcomings can be addressed.

#### Amendment 69

# 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, free of errors and *to the best extent possible* and 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 data sets may be met at the level of individual data sets or a combination thereof.

# Amendment 70

# 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 highrisk AI system is intended to be used.

#### Amendment 71

Proposal for a regulation Article 11 – paragraph 1 – subparagraph 2

PE731.563v02-00 630/665 RR\1279290EN.docx

# 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. Documentation shall be kept up to date throughout its entire lifecycle.

#### Amendment 72

# 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.

#### **Amendment 73**

# 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 *made* otherwise *available*, that include concise, complete, correct and clear information that is relevant, accessible and

comprehensible to users to assist them in operating and maintaining the AI system, taking into consideration the system's intended purpose and the expected audience for the instructions.

#### Amendment 74

# 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 *reasonably* foreseeable circumstances that *could materially* impact that expected level of accuracy, robustness and cybersecurity;

#### Amendment 75

# 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 misuse, which may lead to risks to the health and safety or fundamental rights *or the environment*;

# **Amendment 76**

# Proposal for a regulation Article 13 – paragraph 3 – point e

Text proposed by the Commission

(e) the expected lifetime of the high-

Amendment

(e) the expected lifetime of the high-

PE731.563v02-00 632/665 RR\1279290EN.docx

risk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates. risk AI system, the description of the procedure of withdrawing it from use and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.

#### Amendment 77

# 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, unless there is clear evidence that human intervention compromises the safety of the high risk AI system concerned.

# **Amendment 78**

# 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 *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 misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

#### Amendment 79

# 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. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate *and proportionate* to the circumstances:

#### **Amendment 80**

# 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) have an appropriate understanding of 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 81**

# 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 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, unless there is clear evidence that such human intervention is deemed to increase risks or otherwise negatively impact the system's performance.

# **Amendment 82**

PE731.563v02-00 634/665 RR\1279290EN.docx

# 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 put the system into fail-safe mode, put the system into manual control mode or stop the system through a "stop" button or a similar procedure unless there is clear evidence that such human intervention is deemed to increase risks or otherwise negatively impact the system's performance.

#### **Amendment 83**

Proposal for a regulation Article 14 – paragraph 4 – point e a (new)

Text proposed by the Commission

Amendment

(ea) be able to comprehend when a high risk AI system decision is preferable to human oversight.

## **Amendment 84**

# 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.

#### **Amendment 85**

RR\1279290EN.docx 635/665 PE731.563v02-00

# 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 highest* level of accuracy, robustness and cybersecurity *possible*, and perform consistently in those respects throughout their lifecycle.

#### **Amendment 86**

# Proposal for a regulation Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Providers should take all appropriate and feasible measures to ensure that high-risk AI systems are 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 87

# Proposal for a regulation Article 15 – paragraph 3 – subparagraph 3

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* an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

PE731.563v02-00 636/665 RR\1279290EN.docx

#### **Amendment 88**

Proposal for a regulation Article 28 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) 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.

#### **Amendment 89**

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

Text proposed by the Commission

Amendment

6a. This Article only applies to users acting in their professional capacity and not to those using AI in the course of a personal non-professional activity.

#### Amendment 90

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

Text proposed by the Commission

Amendment

6b. 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.

Amendment 91

Proposal for a regulation Article 30 – paragraph 8

#### Text proposed by the Commission

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

#### Amendment

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question. In this regard, particular attention shall be paid to micro, SMEs keeping compliance costs for them at a reasonable level.

#### **Amendment 92**

# Proposal for a regulation Article 33 – paragraph 6

Text proposed by the Commission

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

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 this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

PE731.563v02-00 638/665 RR\1279290EN.docx

#### Amendment 93

# Proposal for a regulation Article 39 a (new)

Text proposed by the Commission

Amendment

Article 39a

Exchange of knowhow and best practices

The Commission shall facilitate regular consultative meetings for the exchange of knowhow and best practices between the Member States' national authorities responsible for notification policy.

#### Amendment 94

Proposal for a regulation Article 40 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

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

- a) ensure that AI systems placed on the market or put into service in the Union are safe and respect Union values and public interests, and strengthen the Union's digital leadership;
- b) promote investment and innovation in AI, as well as competitiveness and growth of the Union market;
- c) enhance multi-stakeholder governance, by ensuring it is inclusive and representative of all relevant European stakeholders (e.g. civil society, researchers industry, SMEs).
- d) contribute to strengthening global

cooperation on standardisation in the field of AI that is consistent with Union values and interests.

The Commission shall request the European standardisation organisations to regularly report on their progress with regard to the above objectives.

#### Amendment 95

# 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

Where harmonised standards 1. referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, after consulting the AI Board referred to in Article 56 and the responsible authorities and organizations for a given sector, 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 96

# 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

#### 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

PE731.563v02-00 640/665 RR\1279290EN.docx

law.

law as well as relevant sector-specific stakeholders.

#### Amendment 97

# 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. 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, safety, the environment and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.

# **Amendment 98**

# Proposal for a regulation Article 52 – title

Text proposed by the Commission

Transparency obligations for *certain* AI systems

Amendment

Transparency obligations for AI systems

#### Amendment 99

Proposal for a regulation Article 52 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Providers of any AI system should document and make available upon request the parameters regarding the environmental impact, 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.

#### Amendment 100

# 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

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 and secure processing of personal data 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 101**

Proposal for a regulation Article 53 – paragraph 1 a (new)

Text proposed by the Commission

#### Amendment

1a. The organisers of AI regulatory sandboxes shall ensure an easy access for SMEs and start-ups by facilitating and supporting their participation.

PE731.563v02-00 642/665 RR\1279290EN.docx

#### **Amendment 102**

# Proposal for a regulation Article 53 – paragraph 1 b (new)

Text proposed by the Commission

#### Amendment

1b. The controllers of personal data referred to in Article 4 (7) of the Regulation (EU) 2016/679 may further process personal data in an AI regulatory sandbox to the extent that it is necessary for the purposes of development, testing and validation of AI systems. Right of processing is subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. This processing shall not be considered incompatible with the initial purposes.

#### **Amendment 103**

# 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, safety, *the environment or* 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 104**

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 shall coordinate their activities with regards to AI regulatory sandboxes 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 105

Proposal for a regulation Article 54 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) safety and resilience of transport systems, infrastructure and networks.

#### Amendment 106

Proposal for a regulation Article 55 – title

Text proposed by the Commission

Amendment

Measures for *small-scale providers* and users

Measures for SMEs, start-ups and users

Amendment 107

Proposal for a regulation Article 55 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) provide *small-scale providers* and

(a) provide *SMEs* and start-ups with

PE731.563v02-00 644/665 RR\1279290EN.docx

start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

#### **Amendment 108**

# 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;

#### **Amendment 109**

# 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* and user, *start-ups* and other innovators to provide guidance and respond to queries about the implementation of this Regulation.

## **Amendment 110**

Proposal for a regulation Article 55 – paragraph 2 a (new)

Text proposed by the Commission

## Amendment

2a. Where appropriate, Member States shall find synergies and cooperate with relevant instruments funded by Union programmes, such as the European Digital Innovation Hubs.

#### **Amendment 111**

RR\1279290EN.docx 645/665 PE731.563v02-00

# 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, *AI* ethics experts and industry representatives. Other national, regional and local authorities may be invited to the meetings, where the issues discussed are of relevance for them.

#### **Amendment 112**

# 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 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.

# **Amendment 113**

Proposal for a regulation Article 57 – paragraph 3 a (new)

Text proposed by the Commission

#### Amendment

3a. The Board shall organise consultations with stakeholders at least twice a year. Such stakeholders shall include representatives from industry,

PE731.563v02-00 646/665 RR\1279290EN.docx

SMEs and start-ups, 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.

#### **Amendment 114**

# 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 Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups. The Board shall actively reach out to and hear representatives from groups, which are more vulnerable to discriminatory effects posed by AI, such as people with disabilities.

#### **Amendment 115**

# 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

#### Amendment

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

RR\1279290EN.docx 647/665 PE731.563v02-00

understanding of artificial intelligence technologies, data and data computing, fundamental rights, health *and* safety risks and knowledge of existing standards and legal requirements. understanding of artificial intelligence technologies, data and data computing, fundamental rights, health, safety *and environmental* risks and knowledge of existing standards and legal requirements.

#### **Amendment 116**

Proposal for a regulation Article 59 – paragraph 4 a (new)

Text proposed by the Commission

#### Amendment

4a. 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.

#### **Amendment 117**

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, easily navigable and machine-readable*.

#### **Amendment 118**

Proposal for a regulation Article 60 – paragraph 5 a (new)

Text proposed by the Commission

#### Amendment

5a. Any information and documentation obtained by the Commission and Member States pursuant to this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

PE731.563v02-00 648/665 RR\1279290EN.docx

### 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 highrisk 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.

#### **Amendment 120**

#### 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 health, safety *or the environment*, or to the protection of fundamental rights of persons are concerned.

#### Amendment 121

#### Proposal for a regulation Article 67 – paragraph 1

Text proposed by the Commission

1. Where, having performed an

#### Amendment

1. Where, having performed an

RR\1279290EN.docx 649/665 PE731.563v02-00

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.

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 environment, 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 122**

### 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

by national, regional or local authorities, 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 123**

#### 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;

PE731.563v02-00 650/665 RR\1279290EN.docx

taking into account the number of subjects affected and the level of damage suffered by them, the intentional or negligent character of the infringement and any relevant previous infringement;

#### **Amendment 124**

Proposal for a regulation Article 72 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the degree of cooperation with the supervisory authority, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

#### **Amendment 125**

Proposal for a regulation Article 72 – paragraph 1 – point b b (new)

Text proposed by the Commission

Amendment

(bb) any action taken by the provider to mitigate the damage suffered by subjects;

#### **Amendment 126**

Proposal for a regulation Article 72 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) 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.

#### Amendment 127

#### Proposal for a regulation Article 75 – paragraph 1

Regulation (EC) No 300/2008 Article 4 – paragraph 3 – subparagraph 3

Text proposed by the Commission

When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.

#### **Amendment 128**

**Proposal for a regulation Article 76 – paragraph 1**Regulation (EU) No 167/2013
Article 17 – paragraph 5 – subparagraph 3

Text proposed by the Commission

When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment

When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, without interfering with existing governance, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account.

#### Amendment

When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, without interfering with existing governance, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

PE731.563v02-00 652/665 RR\1279290EN.docx

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

#### Proposal for a regulation Article 78 – paragraph 1 Directive 2014/90/EU Article 8 – paragraph 4

Text proposed by the Commission

4. "For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.

#### **Amendment 130**

Proposal for a regulation Article 79 – paragraph 1 Directive (EU) 2016/797 Article 5 – paragraph 12

*Text proposed by the Commission* 

12. "When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment

4. "For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, and without interfering with existing governance, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.

#### Amendment

12. "When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, without interfering with existing governance, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

Proposal for a regulation Article 80 – paragraph 1 Regulation (EU) 2018/858 Article 5 – paragraph 4

Text proposed by the Commission

4. "When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council \*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment

4. "When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council \*, without interfering with existing governance, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### **Amendment 132**

Proposal for a regulation Article 81 – paragraph 1 – point 1 Regulation (EU) 2018/1139 Article 17 – paragraph 3

Text proposed by the Commission

3. "Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be

#### Amendment

3. "Without prejudice to paragraph 2, and to the certification, oversight and enforcement system referred to in Article 62 of this Regulation, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European

PE731.563v02-00 654/665 RR\1279290EN.docx

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

taken into account.

Parliament and of the Council\*, *only* the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account

#### **Amendment 133**

Proposal for a regulation Article 81 – paragraph 1 – point 2 Regulation (EU) 2018/1139 Article 19 – paragraph 4

Text proposed by the Commission

4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment

4. Without prejudice to the certification, oversight and enforcement system referred to in Article 62 of this Regulation, when adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation(EU) YYY/XX [on Artificial Intelligence], only the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### **Amendment 134**

Proposal for a regulation Article 81 – paragraph 1 – point 3 Regulation (EU) 2018/1139 Article 43 – paragraph 4

Text proposed by the Commission

4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall

#### Amendment

4. Without prejudice to the certification, oversight and enforcement system referred to in Article 62 of this Regulation, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of

RR\1279290EN.docx 655/665 PE731.563v02-00

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

be taken into account.

Regulation (EU) YYY/XX[on Artificial Intelligence], *only* the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account

#### **Amendment 135**

Proposal for a regulation Article 81 – paragraph 1 – point 4 Regulation (EU) 2018/1139 Article 47 – paragraph 3

Text proposed by the Commission

3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment

3. Without prejudice to the certification, oversight and enforcement system referred to in Article 62 of this Regulation, when adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation(EU) YYY/XX [on Artificial Intelligence], only the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment 136

Proposal for a regulation Article 81 – paragraph 1 – point 5 Regulation (EU) 2018/1139 Article 57 – paragraph 3

Text proposed by the Commission

When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### Amendment

Without prejudice to the certification, oversight and enforcement system referred to in Article 62of this Regulation, when adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], only the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."

PE731.563v02-00 656/665 RR\1279290EN.docx

Proposal for a regulation Article 81 – paragraph 1 – point 6 Regulation (EU) 2018/1139 Article 58 – paragraph 3

Text proposed by the Commission

3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account..

#### Amendment

3. Without prejudice to the certification, oversight and enforcement system referred to in Article 62 of this Regulation, when adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation(EU) YYY/XX [on Artificial Intelligence], only the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

#### **Amendment 138**

Proposal for a regulation Article 82 – paragraph 1 Regulation (EU) 2019/2144 Article 11

Text proposed by the Commission

3. "When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

3. "When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation(EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, without interfering with existing governance, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

Amendment

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

Proposal for a regulation Article 84 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. 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 energy use and other environmental impact of AI systems and evaluate bringing legislation to regulate the energy efficiency of ICT systems in order for the sector to contribute to Union climate strategy and targets.

#### **Amendment 140**

Proposal for a regulation Article 84 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. Any relevant future delegated or implementing acts to Regulations listed in Annex II, section B, introducing mandatory requirements for High-Risk AI systems laid down in this Regulation, shall take into account the regulatory specificities of each sector and shall not overlap with existing governance, conformity assessment, and enforcement mechanisms and authorities established therein.

**Amendment 141** 

Proposal for a regulation Annex I – title

*Text proposed by the Commission* 

Amendment

ARTIFICIAL INTELLIGENCE

ARTIFICIAL INTELLIGENCE

PE731.563v02-00 658/665 RR\1279290EN.docx

EN

# TECHNIQUES AND *APPROACHESreferred* to in Article 3, point 1

## TECHNIQUES AND *APPROACHES referred* to in Article 3, point 1

#### **Amendment 142**

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.

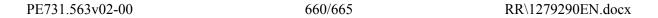
#### Amendment

(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, unless these systems are regulated in harmonisation legislation or sectorial regulation.

RR\1279290EN.docx 659/665 PE731.563v02-00

### ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR FOR THE OPINION HAS RECEIVED INPUT

- BEUC
- ETF
- Google
- Amazon
- Airbus
- Hitachi
- DG MOVE
- DG Connect
- EASA
- AMCHAM
- ACEA
- CLEPA
- Ericsson



### PROCEDURE - COMMITTEE ASKED FOR OPINION

Title	Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts
References	COM(2021)0206 - C9-0146/2021 - 2021/0106(COD)
Committees responsible Date announced in plenary	IMCO LIBE 7.6.2021 7.6.2021
Opinion by Date announced in plenary	TRAN 7.6.2021
Rapporteur for the opinion  Date appointed	Josianne Cutajar 4.11.2021
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021
Discussed in committee	20.4.2022
Date adopted	12.7.2022
Result of final vote	+: 37 -: 1 0: 4
Members present for the final vote	Magdalena Adamowicz, Andris Ameriks, Izaskun Bilbao Barandica, Karolin Braunsberger-Reinhold, Marco Campomenosi, Ciarán Cuffe, Karima Delli, Anna Deparnay-Grunenberg, Ismail Ertug, Gheorghe Falcă, Carlo Fidanza, Søren Gade, Isabel García Muñoz, Jens Gieseke, Elsi Katainen, Kateřina Konečná, Bogusław Liberadzki, Peter Lundgren, Benoît Lutgen, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Tilly Metz, Cláudia Monteiro de Aguiar, Jan-Christoph Oetjen, Rovana Plumb, Dominique Riquet, Massimiliano Salini, Barbara Thaler, István Ujhelyi, Petar Vitanov, Roberts Zīle, Kosma Złotowski
Substitutes present for the final vote	Josianne Cutajar, Nicola Danti, Vlad Gheorghe, Roman Haider, Pär Holmgren, Guido Reil, Marianne Vind, Jörgen Warborn
Substitutes under Rule 209(7) present for the final vote	Susanna Ceccardi, Salvatore De Meo

### FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

37	+
ECR	Carlo Fidanza, Peter Lundgren, Roberts Zīle, Kosma Złotowski
PPE	Magdalena Adamowicz, Karolin Braunsberger-Reinhold, Salvatore De Meo, Gheorghe Falcă, Jens Gieseke, Elżbieta Katarzyna Łukacijewska, Benoît Lutgen, Marian-Jean Marinescu, Cláudia Monteiro de Aguiar, Massimiliano Salini, Barbara Thaler, Jörgen Warborn,
RENEW	Izaskun Bilbao Barandica, Nicola Danti, Søren Gade, Vlad Gheorghe, Elsi Katainen, Jan-Christoph Oetjen, Dominique Riquet
S&D	Andris Ameriks, Josianne Cutajar, Ismail Ertug, Isabel García Muñoz, Bogusław Liberadzki, Rovana Plumb, István Ujhelyi, Marianne Vind, Petar Vitanov
Verts/ALE	Ciarán Cuffe, Karima Delli, Anna Deparnay-Grunenberg, Pär Holmgren, Tilly Metz

1	-
The Left	Kateřina Konečná

4	0
ID	Marco Campomenosi, Susanna Ceccardi, Roman Haider, Guido Reil

Key to symbols: + : in favour - : against 0 : abstention

PE731.563v02-00 662/665 RR\1279290EN.docx

### PROCEDURE - COMMITTEE RESPONSIBLE

Title	Harmonised rules and amending cer			al Intelligence Act)
References	COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)			
Date submitted to Parliament	22.4.2021			
Committees responsible Date announced in plenary	IMCO 7.6.2021	LIBE 7.6.2021		
Committees asked for opinions Date announced in plenary	ENVI 7.6.2021	ITRE 7.6.2021	TRAN 7.6.2021	CULT 7.6.2021
	JURI 7.6.2021			
Associated committees Date announced in plenary	CULT 16.12.2021	ITRE 16.12.2021	JURI 16.12.2021	
Rapporteurs Date appointed	Brando Benifei 1.12.2021	Dragoş Tudorache 1.12.2021		
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021			
Discussed in committee	25.1.2022	21.3.2022	11.5.2022	30.6.2022
	26.10.2022			
Date adopted	11.5.2023			
Result of final vote	+:	83		
	-: 0:	7 12		
Members present for the final vote	Magdalena Adamowicz, Alex Agius Saliba, Abir Al-Sahlani, Andrus Ansip, Katarina Barley, Pietro Bartolo, Alessandra Basso, Brando Benifei, Theresa Bielowski, Vladimír Bilčík, Malin Björk, Vasile Blaga, Biljana Borzan, Vlad-Marius Botoş, Patrick Breyer, Saskia Bricmont, Anna Cavazzini, Patricia Chagnon, Dita Charanzová, Deirdre Clune, David Cormand, Anna Júlia Donáth, Lena Düpont, Lucia Ďuriš Nicholsonová, Cornelia Ernst, Laura Ferrara, Nicolaus Fest, Jean-Paul Garraud, Alexandra Geese, Sandro Gozi, Sylvie Guillaume, Svenja Hahn, Krzysztof Hetman, Evin Incir, Sophia in 't Veld, Virginie Joron, Eugen Jurzyca, Marina Kaljurand, Fabienne Keller, Łukasz Kohut, Arba Kokalari, Marcel Kolaja, Kateřina Konečná, Moritz Körner, Alice Kuhnke, Jean-Lin Lacapelle, Maria-Manuel Leitão-Marques, Jeroen Lenaers, Juan Fernando López Aguilar, Morten Løkkegaard, Antonius Manders, Lukas Mandl, Erik Marquardt, Leszek Miller, Nadine Morano, Javier Moreno Sánchez, Anne-Sophie Pelletier, Paulo Rangel, René Repasi, Karlo Ressler, Diana Riba i Giner, Isabel Santos, Christel Schaldemose, Andreas Schwab, Birgit Sippel, Vincenzo Sofo, Tomislav Sokol, Ivan Štefanec, Annalisa Tardino, Tomas Tobé, Yana Toom, Milan Uhrík, Kim Van Sparrentak, Anders Vistisen, Marion Walsmann, Jadwiga Wiśniewska, Javier Zarzalejos			
Substitutes present for the final vote	Maria da Graça C	Carvalho, Pilar de	l Castillo Vera, G	eoffroy Didier, José

	Gusmão, Katrin Langensiepen, Karen Melchior, Janina Ochojska, Jan-Christoph Oetjen, Tsvetelina Penkova, Rob Rooken, Róża Thun und Hohenstein, Isabella Tovaglieri, Dragoş Tudorache, Miguel Urbán Crespo, Petar Vitanov, Tomáš Zdechovský, Kosma Złotowski
Substitutes under Rule 209(7) present for the final vote	Pascal Arimont, Beatrice Covassi, Alicia Homs Ginel, Peter Jahr, Adam Jarubas, Camilla Laureti, Eva Maydell, Andrey Novakov
Date tabled	22.5.2023

PE731.563v02-00 664/665 RR\1279290EN.docx

### FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

83	+
ECR	Rob Rooken, Jadwiga Wiśniewska, Kosma Złotowski
ID	Patricia Chagnon, Jean-Paul Garraud, Virginie Joron, Jean-Lin Lacapelle
NI	Laura Ferrara, Milan Uhrík
PPE	Magdalena Adamowicz, Pascal Arimont, Vladimír Bilčík, Vasile Blaga, Maria da Graça Carvalho, Pilar del Castillo Vera, Deirdre Clune, Geoffroy Didier, Lena Düpont, Krzysztof Hetman, Peter Jahr, Adam Jarubas, Jeroen Lenaers, Antonius Manders, Lukas Mandl, Eva Maydell, Nadine Morano, Andrey Novakov, Janina Ochojska, Paulo Rangel, Karlo Ressler, Tomislav Sokol, Ivan Štefanec, Marion Walsmann, Javier Zarzalejos, Tomáš Zdechovský
Renew	Abir Al-Sahlani, Vlad-Marius Botoş, Anna Júlia Donáth, Lucia Ďuriš Nicholsonová, Sandro Gozi, Svenja Hahn, Sophia in 't Veld, Fabienne Keller, Moritz Körner, Karen Melchior, Jan-Christoph Oetjen, Róża Thun und Hohenstein, Yana Toom, Dragoş Tudorache
S&D	Alex Agius Saliba, Katarina Barley, Pietro Bartolo, Brando Benifei, Theresa Bielowski, Biljana Borzan, Beatrice Covassi, Sylvie Guillaume, Alicia Homs Ginel, Evin Incir, Marina Kaljurand, Łukasz Kohut, Camilla Laureti, Maria-Manuel Leitão-Marques, Juan Fernando López Aguilar, Leszek Miller, Javier Moreno Sánchez, Tsvetelina Penkova, René Repasi, Isabel Santos, Christel Schaldemose, Birgit Sippel, Petar Vitanov
Verts/ALE	Patrick Breyer, Saskia Bricmont, Anna Cavazzini, David Cormand, Alexandra Geese, Marcel Kolaja, Alice Kuhnke, Katrin Langensiepen, Erik Marquardt, Diana Riba i Giner, Kim Van Sparrentak

7	-
ECR	Eugen Jurzyca
PPE	Arba Kokalari, Tomas Tobé
The Left	Cornelia Ernst, Kateřina Konečná, Anne-Sophie Pelletier, Miguel Urbán Crespo

12	0
ECR	Vincenzo Sofo
ID	Alessandra Basso, Nicolaus Fest, Annalisa Tardino, Isabella Tovaglieri, Anders Vistisen
PPE	Andreas Schwab
Renew	Andrus Ansip, Dita Charanzová, Morten Løkkegaard
The Left	Malin Björk, José Gusmão

Key to symbols: + : in favour - : against 0 : abstention

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