



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

01/06/2022

AMENDMENTS: 484

Brando Benifei, Dragoș Tudorache

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

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

Amendments created with

at4am

Go to <http://www.at4am.ep.parl.union.eu>

\000000EN.doc

Amendments per language:

EN: 484

Amendments justification with more than 500 chars : 0

Amendments justification number with more than 500 chars :

Amendment 1

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Citation 5 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 2

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Citation 5 b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 3

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

***(3 a) In order for Member States to
reach the carbon neutrality targets,
European companies should seek to
utilise all available technological
advancements that can assist in realising
this goal. AI is a well-developed and
ready-to-use technology that can be used
to process the ever-growing amount of
data created during industrial,
environmental, health and other***

processes. To facilitate investments in AI-based analysis and optimisation solutions, this Regulation should provide a predictable and proportionate environment for low-risk industrial solutions.

Or. en

Amendment 4

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 5

Text proposed by the Commission

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

Amendment

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

by the European Parliament³⁴.

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

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

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

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

Or. en

Amendment 5

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 5 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 6

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 5 b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 7
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 6

Text proposed by the Commission

Amendment

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be

(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. ***This definition should be in***

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.*

line with definitions that have found international acceptance. Moreover, it should be based on the key functional characteristics of artificial intelligence distinguishing it from more classic software systems and modelling approaches such as logistic regression and other techniques that are similarly transparent, explainable and interpretable. For the purposes of this Regulation, the definition should be based on the key functional characteristics of the AI system, in particular its ability, for a given set of human-defined objectives, to make predictions, recommendations, or decisions that influence real or virtual environments, whereby it uses machine and/or human-based data and inputs to (i) perceive real and/or virtual environments; (ii) abstract these perceptions into models through analysis in an automated manner (e.g. with machine learning), or manually; and (iii) use model inference to formulate options for outcomes. AI systems are designed to operate with varying levels of autonomy and can be used on a stand-alone software system, integrated into a physical product (embedded), used to serve the functionality of a physical product without being integrated therein (non-embedded) or used as a subsystem of a software/physical/hybrid system of systems. If an AI system is used as a subsystem of a system of systems, then all parts including their interfaces to other parts of the system of systems that would be obsolete if the AI functionality were turned off or removed are essential parts of the AI system thus fall directly under this regulation. Any parts of the system of systems to which this does not hold true are not covered by this regulation and the obligations listed in this regulation do not apply to them. This is to ensure that the integration of AI systems into existing

systems is not blocked by this regulation.

Or. en

Amendment 8

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 6 a (new)

Text proposed by the Commission

Amendment

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

Amendment 9

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 6 b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 10

Axel Voss, Deirdre Clune

Proposal for a regulation

Recital 8

Text proposed by the Commission

Amendment

(8) The notion of remote biometric

(8) The notion of remote biometric

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

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

Or. en

Amendment 11

Axel Voss, Deirdre Clune, Eva Maydell

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

Amendment

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

third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.

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

Or. en

Amendment 12
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 13
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission

Amendment

(15 a) As signatories to the United Nations Convention on the Rights of

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

Or. en

Amendment 14

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 16

Text proposed by the Commission

(16) The placing on the market, putting into service or use of certain AI systems ***intended to distort*** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components ***individuals*** cannot perceive or exploit vulnerabilities of ***children and people*** due to their age, ***physical or mental incapacities***. ***They do so*** with the ***intention to*** materially ***distort*** the behaviour of a person and in a manner that causes or is

Amendment

(16) The placing on the market, putting into service or use of certain AI systems ***materially distorting*** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components ***that persons*** cannot perceive or ***those systems otherwise*** exploit vulnerabilities of ***a specific group of persons*** due to their age, ***disability within the meaning of Directive (EU) 2019/882, or social or economic situation***. ***Such***

likely to cause harm to that or another person. The intention may not be presumed if the distortion *of human behaviour* results from factors external to the AI system which are outside of the control of the provider or the user. *Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.*

systems can be placed on the market, put into service or used with the objective to or the effect of materially distorting the behaviour of a person and in a manner that causes or is reasonably likely to cause physical or psychological harm to that or another person or groups of persons, including harms that may be accumulated over time. The intention to distort the behaviour may not be presumed if the distortion results from factors external to the AI system which are outside of the control of the provider or the user meaning factors that may not be reasonably foreseen and mitigated by the provider or the user of the AI system. In any case, it is not necessary for the provider or the user to have the intention to cause the physical or psychological harm, as long as such harm results from the manipulative or exploitative AI-enabled practices. The prohibitions for such AI practices is complementary to the provisions contained in Directive [Unfair Commercial Practice Directive 2005/29/EC, as amended by Directive (EU) 2019/216], notably that unfair commercial practices leading to economic or financial harms to consumers are prohibited under all circumstances, irrespective of whether they are put in place through AI systems or otherwise.

Or. en

Amendment 15

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17 a) AI systems that are intended for use to protect consumers and prevent fraudulent activities should not necessarily be considered high-risk under

this Regulation. As set by Article 94 of the Directive (EU) 2015/2366, payment systems and payment service providers should be allowed to process data to safeguard the prevention, investigation and detection of payment fraud. Therefore AI systems used to process data to safeguard the prevention, investigation and detection of fraud may not be considered as high-risk AI systems for the purpose of this Regulation.

Or. en

Amendment 16
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 27

Text proposed by the Commission

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

Amendment

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

restriction to international trade, if any.

Or. en

Amendment 17

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 29

Text proposed by the Commission

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

Amendment

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

acts on the basis of those acts.

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

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

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

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

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

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

⁴⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a

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

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

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

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

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

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

⁴⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a

European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

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

European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

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

Or. en

Amendment 18

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 30

Text proposed by the Commission

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

Amendment

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation (*as specified in Annex II*), it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

Or. en

Amendment 19

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 31

Text proposed by the Commission

(31) The classification of an AI system as high-risk pursuant to this Regulation ***should not necessarily*** mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered ‘high-risk’ under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council⁴⁷ and Regulation (EU) 2017/746 of the European Parliament and of the Council⁴⁸, ***where a***

Amendment

(31) The classification of an AI system as high-risk pursuant to this Regulation ***shall not*** mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered ‘high-risk’ under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council⁴⁷ and Regulation (EU) 2017/746 of the European Parliament and

third-party conformity assessment is provided for medium-risk and high-risk products.

⁴⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁴⁸ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

of the Council⁴⁸.

⁴⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁴⁸ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Amendment 20

Axel Voss, Deirdre Clune

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Amendment

(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, ‘real-time’ and ‘post’ remote biometric identification systems should be classified as high-risk, ***except for the purpose of remote client on-boarding or verification of a user through a device***. In view of the risks that they ***may*** pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and, ***when appropriate and justified by a***

proven added value to the protection of health, safety and fundamental rights, human oversight.

Or. en

Amendment 21

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 34

Text proposed by the Commission

(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

Amendment

(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety ***or security*** components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may ***infringe the security and integrity of such critical infrastructure and thus*** put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

Or. en

Amendment 22

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 36

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination ***and for task allocation***, monitoring or evaluation of persons in work-related contractual relationships, should also be

Amendment

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since

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.

those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Or. en

Amendment 23

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 41

Text proposed by the Commission

(41) The fact that an AI system is ***classified as high risk*** under this Regulation should not be interpreted as indicating that the use of the system is necessarily ***lawful*** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of

Amendment

(41) The fact that an AI system is ***compliant with the requirements for high-risk AI*** under this Regulation should not be interpreted as indicating that the use of the system is necessarily ***unlawful*** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of

secondary Union law and national law.
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.

secondary Union law and national law. As
far as is applicable and proportionate, this
Regulation *may, where duly justified*, be
understood as providing for the legal
ground for processing of personal data
where relevant.

Or. en

Amendment 24

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 41 a (new)

Text proposed by the Commission

Amendment

(41 a) AI systems do not operate in a lawless world. A number of legally binding rules at European, national and international level already apply or are relevant to AI systems today. Legal sources include, but are not limited to EU primary law (the Treaties of the European Union and its Charter of Fundamental Rights), EU secondary law (such as the General Data Protection Regulation, the Product Liability Directive, the Regulation on the Free Flow of Non-Personal Data, anti-discrimination Directives, consumer law and Safety and Health at Work Directives), the UN Human Rights treaties and the Council of Europe conventions (such as the European Convention on Human Rights), and numerous EU Member State laws. Besides horizontally applicable rules, various domain-specific rules exist that apply to particular AI applications (such as for instance the Medical Device Regulation in the healthcare sector).

Or. en

Amendment 25

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system, ***level of reliance of the user or business user on the output of the AI system for the final decision or outcome*** and according to the risk management system to be established by the provider.

Or. en

Amendment 26
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 44

Text proposed by the Commission

(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative ***and free of errors and complete*** in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is

Amendment

(44) High data quality ***and having simple and accessible data plays a vital role in providing structure and ground truth for AI and*** is essential for ***purpose-ready data analytics and*** the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. ***To achieve simple access to and usability of high quality data for AI, the Commission shall examine ways to facilitate the lawful processing of personal data to train legitimate AI systems by appropriate amendments to applicable laws.*** High quality training, validation and testing data sets require the

intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers *should be* able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

implementation of appropriate data governance and management practices. Training, *machine learning* validation and testing data sets should be sufficiently relevant *and* representative in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, *machine learning* validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. *If it is necessary for the aforementioned purpose to use existing sets of data that includes personal data originally collected and stored for a different purpose their use for the aforementioned purpose shall be deemed compatible with the original purpose so long as the personal data is not transferred to any third party.* In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers *should be* able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 27

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 45

Text proposed by the Commission

(45) For the development of high-risk

Amendment

(45) For the development *and*

AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

assessment of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

Or. en

Amendment 28

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 46

Text proposed by the Commission

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their **lifetime** is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical

Amendment

(46) Having information on how high-risk AI systems have been developed and how they perform throughout their **lifetime** is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation,

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.

containing information which is necessary to assess the compliance of the AI system with the relevant requirements, *while preserving trade secrets*. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Or. en

Amendment 29

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 48

Text proposed by the Commission

(48) High-risk AI systems should be designed and developed in such a way that natural persons *can* oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints *that cannot be overridden by the system itself and is* responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Amendment

(48) High-risk AI systems should be designed and developed in such a way that natural persons *may, when appropriate, oversee their functioning*. For this purpose, *when it brings proven added value to the protection of health, safety and fundamental rights*, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints *and are* responsive to the human operator *during the expected lifetime of the device where necessary to reduce risks as far as possible and achieve performance in consideration of the generally acknowledged state-of-the-art and technological and scientific progress*, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. *By way of derogation regarding high-risk AI systems*

within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the Council, the established benefit-risk ratio requirements under the sectoral medical device legislation shall apply.

Or. en

Amendment 30

Axel Voss, Deirdre Clune, Eva Maydell

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 ***lifetime*** and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the users. ***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 shall bring together national metrology and benchmarking authorities and provide guidance to address the technical aspects of how to measure the appropriate levels of accuracy and robustness. Their work shall not be seen as a replacement of the standardisation organisations, but as a complementary function to provide specific technical expertise on measurement.***

Or. en

Amendment 31

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 51

Text proposed by the Commission

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, *suitable* measures should therefore be taken by the providers of high-risk AI systems, *also taking into account as appropriate the* underlying ICT infrastructure.

Amendment

(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, *state-of-the-art* measures should therefore be taken *into account* by the providers of high-risk AI systems *but also by the national competent authorities, market surveillance authorities and notified bodies that are accessing the data of providers of high-risk AI systems, next to* appropriate underlying ICT infrastructure. *It shall be further taken into account that AI in the form of machine learning is a critical defence against malware representing a legitimate interest of the AI user.*

Or. en

Amendment 32
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 60

Text proposed by the Commission

(60) In the light of the complexity of the artificial intelligence value chain, relevant

Amendment

(60) In the light of the complexity of the artificial intelligence value chain, relevant

third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.

third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation. ***This provision shall qualify as a legal obligation in the context of the processing of personal data where necessary for the cooperation between the relevant providers.***

Or. en

Amendment 33

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 62

Text proposed by the Commission

(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.

Amendment

(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service. ***AI systems, including general purpose AI systems, that may not necessarily be high-risk, are frequently used as components of other AI or non-AI software systems. In order to increase trust in the value chain and to give certainty to businesses about the performance of their systems, providers may voluntarily apply for a third-party conformity assessment.***

Or. en

Amendment 34

Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 65

Text proposed by the Commission

(65) In order to carry out third-party conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence **and** absence of conflicts of interests.

Amendment

(65) In order to carry out third-party conformity assessment for AI systems intended to be used for the remote biometric identification of persons, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence, absence of conflicts of interests **and minimum cybersecurity requirements**.

Or. en

Amendment 35
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 66

Text proposed by the Commission

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been **pre-determined** by the provider and assessed at the moment of the conformity assessment should not constitute a substantial

Amendment

(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may **create a new or increased risk and significantly** affect the compliance of the system with this Regulation or when the intended purpose of the system changes. ***If such a case materialises, the provider should follow a clear procedure with fixed deadlines, transparency requirements and reporting duties involving, where appropriate and applicable, external oversight by notified bodies or, where it is covered already under the relevant sectoral legislation, post market monitoring if that is needed.*** In addition, as regards AI systems which

modification.

continue to ‘learn’ after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been *considered* by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification. *In addition, it should not be considered as a substantial modification if the user trains an AI system. In this situation, the user should clearly delimit the effects that the learning can have for the AI system. The notion of substantial modification should be assessed in light of the essential requirements set in this Regulation and be left to the manufacturer to determine if a modification is deemed to be substantial.*

Or. en

Amendment 36

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 66 a (new)

Text proposed by the Commission

Amendment

(66 a) To prevent any deterioration in the expected safety of the algorithm subject to significant changes independent of the providers control, a clearly developed plan to address such significant changes should be subject to oversight by the relevant competent authorities or notified bodies when it is already addressed in principle in the respective sectoral Union harmonisation legislation regarding post-market monitoring

Or. en

Proposal for a regulation
Recital 70

Text proposed by the Commission

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, 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

(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use ***or where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video game visuals or analogous work***. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose ***in an appropriate, clear and visible manner*** that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 38
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 70 a (new)

Text proposed by the Commission

Amendment

(70 a) In light of the nature and complexity of the value chain for AI systems, it is essential to clarify the role of humans who may contribute to the development of AI systems covered by this Regulation, without being providers, no longer being providers or when other natural or legal persons have also become providers. Therefore, it is particularly important to clarify the legal situation when it comes to general purpose AI systems. Those AI system are able to perform generally applicable functions such as image/speech recognition, audio/video generation, pattern detection, question answering or translation in a plurality of contexts. Every natural or legal person can become a new provider by adapting a general purpose AI system, already placed on the market or put into service, to a specific intended purpose. Due to their peculiar nature and in order to ensure a fair sharing of responsibilities along the AI value chain, such general purpose AI system should however already be subject to proportionate and tailored requirements and obligations under this Regulation even before placing it on the Union market or putting it into service. The original provider of a general purpose AI system should furthermore cooperate, as appropriate, with the new provider to enable its compliance with the relevant obligations under this Regulation.

Or. en

Amendment 39

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 73

Text proposed by the Commission

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

Amendment

(73) In order to promote and protect innovation, it is important that the interests of **SME** providers and users of AI systems are taken into particular account. To this objective, ***AI solutions and services designed to combat fraud and protect consumers against fraudulent activities should not be considered high risk, nor prohibited. As a matter of substantial public interest, it is vital that this Regulation does not undermine the incentive of industry to create and roll out solutions designed to combat fraud across the Union. Furthermore***, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of **SME** providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users. ***Member States should also be encouraged to do the same for small and medium enterprises, which may sometimes lack the requisite administrative and legal resources to ensure proper understanding and compliance with the provisions under this***

act. In the event that Member States request it, the Commission may also provide assistance in this regard.

Or. en

Amendment 40

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 74

Text proposed by the Commission

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

Amendment

(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, ***Member States should utilise existing dedicated channels for communication with SMEs and start-ups. Such existing channels could include but are not limited to ENISA's Computer Security Incident Response Teams, National data protection agencies***, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

Or. en

Amendment 41

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 76 a (new)

(76 a) The Commission should re-establish the High Level Expert Group or a similar body with a new and balanced membership comprising an equal number of experts from SMEs and start-ups, large enterprises, academia and Research, and civil society. This new High Level Expert Group should not only act as advisory body to the Commission but also to the Board. At least every quarter, the new High Level Expert Group must have the chance to share its practical and technical expertise in a special meeting with the Board.

Or. en

Amendment 42

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Recital 80

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European ***Central Bank***, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, ***including for*** market surveillance activities, as regards AI

(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the ***competent*** authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the ***competent authorities as defined in Directive 2013/36/EU of the European Parliament and of the Council***, should be designated as competent authorities for the purpose of supervising

systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

the implementation of this Regulation, ***excluding*** market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council⁵⁶, it is also appropriate to integrate ***certain aspects of*** the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

⁵⁶ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 43 **Axel Voss, Deirdre Clune**

Proposal for a regulation **Recital 84**

Text proposed by the Commission

(84) Member States should take all necessary measures to ensure that the

Amendment

(84) Member States should take all necessary measures to ensure that the

provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.

provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation. ***The penalties and litigation costs under this Regulation should not be subject to contractual clauses or any other arrangements.***

Or. en

Amendment 44

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 1 – paragraph 1 – point e

Text proposed by the Commission

(e) rules on market monitoring ***and*** surveillance.

Amendment

(e) rules on market monitoring, ***market*** surveillance ***and governance***;

Or. en

Amendment 45

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(e a) measures in support of innovation with a particular focus on SMEs and start-ups, including but not limited to setting up regulatory sandboxes and targeted measures to reduce the compliance burden on SME's and start-ups;

Amendment 46

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 1 – paragraph 1 – point e b (new)

Text proposed by the Commission

Amendment

(e b) the establishment of an independent ‘European Artificial Intelligence Board’ and its activities supporting the enforcement of this Regulation.

Or. en

Amendment 47

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) users of AI systems **located** within the Union;

(b) users of AI systems **who are physically present or established** within the Union;

Or. en

Amendment 48

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) providers and users of AI systems that are located in a third country, where the output produced by the system **is used** in the Union;

(c) providers and users of AI systems that are located in a third country, where the output, **meaning predictions, recommendations or decisions**, produced by the **AI** system **and influencing the environment it interacts with, is intended**

for use in the Union and puts at risk the health, safety or fundamental rights of natural persons physically present in the Union, insofar as the provider has permitted, is aware or can reasonably expect such use;

Or. en

Amendment 49

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) importers, distributors and authorised representatives of providers of AI-systems.

Or. en

Amendment 50

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, *falling* within the scope of the *following acts*, only Article 84 of this Regulation shall apply:

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.

Or. en

Amendment 51

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) **Regulation (EC) 300/2008;** *deleted*

Or. en

Amendment 52

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point b

Text proposed by the Commission

Amendment

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

Or. en

Amendment 53

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point c

Text proposed by the Commission

Amendment

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

Or. en

Amendment 54

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) **Directive 2014/90/EU;** *deleted*

Or. en

Amendment 55

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(e) *Directive (EU) 2016/797;* *deleted*

Or. en

Amendment 56
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(f) *Regulation (EU) 2018/858;* *deleted*

Or. en

Amendment 57
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(g) *Regulation (EU) 2018/1139;* *deleted*

Or. en

Amendment 58
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(h) *Regulation (EU) 2019/2144.* *deleted*

Or. en

Amendment 59

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 3

Text proposed by the Commission

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.

Amendment

3. This Regulation shall not apply to AI systems developed or used exclusively for military *or national security* purposes

Or. en

Amendment 60

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Title III of this Regulation shall not apply to AI systems that are used in a business-to-business environment and do not directly impact natural persons.

Or. en

Amendment 61

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 2 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. This Regulation shall not affect any research, testing and development activity regarding an AI system prior to this system being placed on the market or put into service.

Or. en

Amendment 62
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

5 b. This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research, testing and development. The Commission may adopt delegated acts that clarify this exemption.

Or. en

Amendment 63
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(1) ‘artificial intelligence system’ (AI system) means **software** that is developed with one or more of the techniques and approaches listed in Annex I and **can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;**

(1) ‘artificial intelligence system’ (AI system) means **a machine-based system** that is developed with one or more of the techniques and approaches listed in Annex I and **is capable of influencing the environment by producing an output**(predictions, recommendations, or decisions) **for a given set of objectives. It uses machine and/or human-based data and inputs to (i) perceive real and/or virtual environments; (ii) abstract these perceptions into models through analysis in an automated manner (e.g. with machine learning), or manually; and (iii) use model inference to formulate options for outcomes. AI systems are designed to operate with varying levels of autonomy;**

Or. en

Unchanged OECD definition

Amendment 64

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

Amendment

(1 a) ‘machine learning’ means an AI system that gives computers the ability to find patterns in data without being explicitly programmed for a given task;

Or. en

Amendment 65

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1 b) ‘general purpose AI system’ means an AI system that - irrespective of the modality in which it is placed on the market or put into service including as open source software - is able to perform generally applicable functions such as image or speech recognition, audio or video generation, pattern detection, question answering, translation or others; a general purpose AI system may be used in a plurality of contexts and may be integrated in a plurality of other AI systems;

Or. en

Amendment 66

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(1 c) ‘autonomous’ means an AI-system that operates by interpreting certain input and results and by using a set of pre-determined objectives, without being limited to such instructions, despite the system’s behaviour being constrained by, and targeted at, fulfilling the goal it was given and other relevant design choices made by its provider;

Or. en

Justification

Unchanged definition from AI Whitepaper (Commission)

Amendment 67
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(1 d) ‘risk’ means the combination of the probability of occurrence of a harm and the severity of that harm;

Or. en

Amendment 68
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(1 e) ‘harm’ means an adverse impact affecting the health, safety or

fundamental rights of a natural person;

Or. en

Amendment 69

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that *develops* an AI system *or that has an AI system developed with a view to placing it* on the market or *putting* it into service under its own name or trademark, whether for payment or free of charge;

Amendment

(2) ‘provider’ means a natural or legal person, public authority, agency or other body that *places* an AI system on the market or *puts* it into service under its own name or trademark, whether for payment or free of charge *or that adapts general purpose AI systems to an intended purpose;*

Or. en

Amendment 70

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2 a (new)

Text proposed by the Commission

Amendment

(2 a) ‘*new provider*’ means a natural or legal person that becomes provider for the purposes of this Regulation due to one of the circumstances referred to in Art 23a(1).

Or. en

Amendment 71

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2 b (new)

Text proposed by the Commission

Amendment

(2 b) ‘former provider’ means a provider that initially placed the AI system on the market or put it into service but is according to Art 23a(2) no longer considered a provider for the purposes of this Regulation;

Or. en

Amendment 72

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 2 c (new)

Text proposed by the Commission

Amendment

(2 c) ‘original provider’ means a provider of a general purpose AI system, who has made available the AI system to a natural or legal person that itself became a provider by giving an intended purpose to the general purpose AI system;

Or. en

Amendment 73

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) ‘small-scale provider’ means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC⁶¹ ;

deleted

⁶¹ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L

Amendment 74

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘**user**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Amendment

(4) ‘**deployer**’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

Or. en

Amendment 75

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘authorised representative’ means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

Amendment

(5) ‘authorised representative’ means any natural or legal person **physically present or** established in the Union who has received **and accepted** a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

Or. en

Amendment 76

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

(5 a) ‘product manufacturer’ means a manufacturer within the meaning of any of the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 77

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

(6) ‘importer’ means any natural or legal person established in the Union that places on the market **or puts into service** an AI system that bears the name or trademark of a natural or legal person established outside the Union;

(6) ‘importer’ means any natural or legal person **physically present or** established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established outside the Union;

Or. en

Amendment 78

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 7 a (new)

Text proposed by the Commission

Amendment

(7 a) ‘economic operator’ means the provider, the authorised representative, the importer and the distributor;

Or. en

Amendment 79

Axel Voss, Deirdre Clune, Eva Maydell

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 ***economic operator and*** the user;

Or. en

Amendment 80

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Amendment

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose ***and with the specific context and conditions of use established by the provider***, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Or. en

Amendment 81

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety function for that product or system ***or the failure or malfunctioning of which endangers*** the health and safety of persons ***or property***;

Amendment

(14) ‘safety component of a product or system’ means, ***in line with the relevant Union harmonisation legislation listed in Annex II***, a component of a product or of a system which fulfils a ***direct and critical*** safety function for that product or system ***so that its malfunction endangers*** the health and safety of persons;

Or. en

Amendment 82
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s intended purpose and proper use, ***inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;***

Amendment

(15) ‘instructions for use’ means the information provided by the provider to inform the user of in particular an AI system’s intended purpose and proper use,

Or. en

Amendment 83
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(16) ‘recall of an AI system’ means any measure aimed at achieving the return to the provider of an AI system made available to users;

Amendment

(16) ‘recall of an AI system’ means any measure aimed at achieving the return to the provider ***or taking it out of service or disable the use*** of an AI system made available to users;

Or. en

Amendment 84
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 17

Text proposed by the Commission

(17) ‘withdrawal of an AI system’ means any measure aimed at preventing ***the distribution, display and offer of*** an AI

Amendment

(17) ‘withdrawal of an AI system’ means any measure aimed at preventing an AI system ***in the supply chain being made***

system;

available on the market;

Or. en

Amendment 85

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 20

Text proposed by the Commission

(20) ‘conformity assessment’ means the process of *verifying* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Amendment

(20) ‘conformity assessment’ means the process of *demonstrating* whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Or. en

Amendment 86

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 22

Text proposed by the Commission

(22) ‘notified body’ means a conformity assessment body *designated* in accordance with this Regulation and other relevant Union harmonisation legislation;

Amendment

(22) ‘notified body’ means a conformity assessment body *notified* in accordance with *Art 32 of* this Regulation and *with* other relevant Union harmonisation legislation;

Or. en

Amendment 87

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘substantial modification’ means a change to the AI system following its

Amendment

(23) ‘substantial modification’ means a change to the AI system following its

placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

placing on the market or putting into service, ***not foreseen by the provider***, which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;

Or. en

Amendment 88

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 24

Text proposed by the Commission

(24) ‘CE marking of conformity’ (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing;

Amendment

(24) ‘CE marking of conformity’ (CE marking) means a ***physical or electronic*** marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing ***as well as the GDPR***;

Or. en

Amendment 89

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 28

Text proposed by the Commission

(28) ‘common specifications’ means a document, other than a standard, ***containing technical solutions*** providing a means to, comply with certain requirements and obligations established

Amendment

(28) ‘common specifications’ means a document ***comprising a set of technical specifications***, other than a standard, providing a means to comply with certain requirements and obligations established

under this Regulation;

under this Regulation;

Or. en

Amendment 90

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 30

Text proposed by the Commission

(30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

Amendment

(30) ‘**machine learning** validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

Or. en

Amendment 91

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;

Amendment

(31) ‘testing data’ means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service. ***The testing data must be a separate dataset;***

Or. en

Amendment 92

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 34

Text proposed by the Commission

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric *data*;

Amendment

(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric *or other data obtained, read or interpreted from an individual*;

Or. en

Amendment 93

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through *the* comparison *of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be* identified ;

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a *physical* distance through a *“one to many”* comparison *where the persons identified do not claim to have a particular identity but where the identity is otherwise established - without the conscious cooperation of these persons - by matching live templates with templates stored in a template database*;

Or. en

Amendment 94

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 36 a (new)

Text proposed by the Commission

Amendment

(36 a) ‘at a distance’ means the process of identification, verification or authentication in physical distance with

*indirect interaction with the data subject
or without;*

Or. en

Amendment 95

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 39

Text proposed by the Commission

(39) ‘publicly accessible space’ means any physical place accessible to *the public*, regardless of whether certain conditions for access *may apply*;

Amendment

(39) ‘publicly accessible space’ means any *publicly or privately owned* physical place accessible to *an undetermined number of natural persons*, regardless of whether certain conditions *or circumstances* for access *have been predetermined, and regardless of the potential capacity restrictions*;

Or. en

Amendment 96

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 3 – paragraph 1 – point 41

Text proposed by the Commission

(41) ‘law enforcement’ means activities carried out by law enforcement authorities for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

Amendment

(41) ‘law enforcement’ means activities carried out by law enforcement authorities *or on their behalf* for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

Or. en

Amendment 97

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 98
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 44 – introductory part

Text proposed by the Commission

Amendment

(44) ‘serious incident’ means any
incident that directly or indirectly leads,
might have led or might lead to any of the
following:

(44) ‘serious incident’ means any
incident that directly or indirectly leads to
any of the following:

Or. en

Amendment 99
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 3 – paragraph 1 – point 44 – point a

Text proposed by the Commission

Amendment

(a) the death of a person or serious
damage to a person’s health, *to property or*
the environment,

(a) the death of a person or serious
damage to a person’s health,

Or. en

Amendment 100
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(44 a) ‘regulatory sandbox’ means a framework which, by providing a structured context for experimentation, enable where appropriate in a real-world or digital environment the testing of innovative technologies, products, services or approaches for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place;

Or. en

Amendment 101

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 b (new)

Text proposed by the Commission

Amendment

(44 b) ‘deep fake’ means manipulated or synthetic audio, image or video content that would falsely appear to be authentic or truthful, and which features depictions of persons appearing to say or do things they did not say or do, without their consent, produced using AI techniques, including machine learning and deep learning;

Or. en

Amendment 102

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 c (new)

Text proposed by the Commission

Amendment

(44 c) ‘incident’ means a faulty operation of an AI system;

Amendment 103

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 d (new)

Text proposed by the Commission

Amendment

(44 d) ‘personal data’ means data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;

Or. en

Amendment 104

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 e (new)

Text proposed by the Commission

Amendment

(44 e) ‘non-personal data’ means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;

Or. en

Amendment 105

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 f (new)

Text proposed by the Commission

Amendment

(44 f) ‘critical infrastructure’ means an asset, system or part thereof which is necessary for the delivery of a service that is essential for the maintenance of vital societal functions or economic activities within the meaning of Article 2 (4) and (5) of Directive of the European

Amendment 106

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 g (new)

Text proposed by the Commission

Amendment

*(44 g) ‘harmful subliminal technique’
means a measure whose existence and
operation is entirely imperceptible by a
natural person on whom it is used, and
which has the purpose and direct effect to
induce actions leading to that persons
physical or phychological harm;*

Or. en

Amendment 107

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 3 – paragraph 1 – point 44 h (new)

Text proposed by the Commission

Amendment

*(44 h) 'unfair bias' means an inclination
of prejudice towards or against a natural
person that can result in discriminatory
and/or unfair treatment of some natural
persons with respect to others.*

Or. en

Amendment 108

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of ***characteristics that are similar to the techniques and approaches listed therein.***

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 73, ***after ensuring adequate consultation with relevant stakeholders,*** to amend the list of techniques and approaches listed in Annex I ***within the scope of the definition of an AI system as provided for in Article 3(1),*** in order to update that list to market and technological developments on the basis of ***transparent criteria.***

Every time the list of techniques and approaches listed in Annex I is amended, providers and users of AI systems, which become in scope of the Regulation shall have 24 months to apply the relevant requirements and obligations. Article 83 shall apply for AI systems already placed on the market before delegated acts are published.

Or. en

Amendment 109

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4 a

Trustworthy AI systems

1. The principles set out in this Article establish a high-level framework for a coherent and coordinated human-centric European approach on trustworthy AI systems that respect and promote the values on which the Union is founded. This Regulation takes those principles into account by establishing certain requirements for high-risk AI systems listed in Article 8 to 15.

- *‘human agency and oversight’ means that AI systems shall be developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be controlled and overseen by humans in a manner that is appropriate to the circumstances of the case.*
- *‘technical robustness and safety’ means that AI systems shall be developed and used in a way to minimize unintended and unexpected harm as well as being robust in case of problems and being resilient against attempts to alter the use or performance of the AI system by malicious third parties.*
- *‘privacy and data governance’ means that AI systems shall be developed and used in compliance with existing privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity.*
- *‘transparency’ means that AI systems shall be developed and used in a way that allows appropriate traceability and explainability, while making humans Aware that they communicate or interact with an AI system as well as duly informing users of the capabilities and limitations of that AI system.*
- *‘diversity, non-discrimination and fairness’ means that AI systems shall be developed and used in a way that includes diverse actors and promotes equal access, while avoiding discriminatory impacts that are prohibited by Union or Member States law.*
- *‘social and environmental well-being’ means that AI systems shall be developed and used in a sustainable and environmentally friendly manner as well as in away to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society*

and democracy.

• *‘accountability’ means that AI systems shall be developed or used in a way that facilitates auditability and accountability pursuant to applicable Union and Member States law, while making clear who is legally responsible in case the AI system causes negative impacts.*

2. Paragraph 1 is without prejudice to obligations set up by existing Union and Member States legislation and does not create any additional obligations for providers or users.

3. European Standardisation Organisations shall understand the principles referred to in paragraph 1 as outcome-based objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b). For all other AI systems, the voluntary application on the basis of harmonised standards, technical specifications and codes of conducts as referred to in Article 69(1a) is encouraged.

Or. en

Amendment 110

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

(a) the placing on the market, putting into service or use of an AI system *that deploys subliminal techniques beyond a person’s consciousness in order to materially distort* a person’s behaviour *in a manner that causes or is likely to cause* that person or another person *physical or psychological* harm;

Amendment

(a) the placing on the market, putting into service or use of an AI system *with the objective to significantly and* materially *distorting* a person’s behaviour *or directly causing* that person or another person *significant* harm;

Or. en

Amendment 111

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, ***in order to*** materially ***distort*** the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or 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, ***with the objective to or the effect of*** materially ***distorting*** the behaviour of a person pertaining to that group in a manner that causes or is likely to ***directly*** cause that person or another person ***significant*** harm;

Or. en

Amendment 112

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

(i) detrimental or unfavourable treatment of certain natural persons or ***whole*** groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

Amendment

(i) detrimental or unfavourable treatment of certain natural persons or groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;

Or. en

Amendment 113

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission

(ii) detrimental or unfavourable treatment of certain natural persons or **whole** groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;

Amendment

(ii) detrimental or unfavourable treatment of certain natural persons or groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;

Or. en

Amendment 114

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) the use of ‘real-time’ remote biometric identification **systems** in publicly accessible spaces **for the purpose of** law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:

Amendment

(d) the use of ‘real-time’ remote biometric identification **function of an AI system** in publicly accessible spaces **by** law enforcement **or on their behalf**, unless and in as far as such use is strictly necessary **used** for one of the following objectives:

Or. en

Amendment 115

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

(ii) the prevention of a specific, substantial **and imminent** threat to the **life** or physical safety of natural persons or of a terrorist attack;

Amendment

(ii) the prevention of a specific **and** substantial threat to the **critical infrastructure, life, health** or physical safety of natural persons or of a terrorist attack;

Or. en

Amendment 116

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

(iii) the ***detection***, localisation, identification ***or*** prosecution ***of a perpetrator or suspect of*** a criminal ***offence*** referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.

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

(iii) the localisation ***or*** identification ***of a natural person for the purpose of conducting a criminal investigation***, prosecution ***or executing*** a criminal ***penalty for offences*** referred to in Article 2(2) of Council Framework Decision 2002/584/JHA⁶² and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, ***or other specific offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least five years*** as determined by the law of that Member State.

⁶² Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

Or. en

Amendment 117

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 5 – paragraph 3 – introductory part

Text proposed by the Commission

3. As regards paragraphs 1, point (d) and 2, each ***individual*** use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent

Amendment

3. As regards paragraphs 1, point (d) and 2, each use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent

administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation ***and the*** authorisation ***may be*** requested ***only during or after the use.***

administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation ***if such*** authorisation ***is*** requested ***without undue delay, and, if such authorisation is rejected, the system's use is stopped with immediate effect.***

Or. en

Amendment 118
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Amendment

4. A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision ***and reporting*** relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.

Or. en

Amendment 119

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 1 – introductory part

Text proposed by the Commission

1. *Irrespective of whether* an AI system *is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system* shall be considered *high-risk where both of the following conditions are fulfilled:*

Amendment

1. An AI system *that is itself a product* shall be considered as *high risk AI system if, under the applicable Union harmonisation legislation listed in Annex II, it is classified as high-risk AI system or an equivalent thereof and has to undergo a third-party conformity assessment for meeting essential safety requirements prior to placing it on the market or putting it into service.*

An AI system intended to be used as a core and essential safety component of a product under the applicable Union harmonisation legislation listed in Annex II, shall be considered as high risk if such Union harmonisation legislation classifies it as high-risk or an equivalent thereof and requires it to undergo a third-party conformity assessment for meeting essential safety requirements with a view to placing it on the market or putting it into service.

The high-risk classification set in paragraph 1 shall not impact or determine the outcome of other risk classification procedures established in Union harmonisation legislation listed in Annex II

Or. en

Amendment 120

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(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;*

deleted

Or. en

Amendment 121

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 122

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, **AI systems** referred to in Annex III shall also be considered high-risk.

2. In addition to the high-risk AI systems referred to in paragraph 1, *each AI system with an intended purpose - as specified in its instruction to use in accordance with Art 3(12) and Art 13(2) - that means that it will be deployed in a way that falls under one of the critical use cases* referred to in Annex III shall also be

considered high-risk *if that AI system will make a final decision that puts significantly at risk the health, safety or fundamental rights of natural persons.*

Or. en

Amendment 123

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 6 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *The assessment by the provider of whether an AI system puts at risk the health, safety or fundamental rights of natural persons shall also take into account the factors enumerated in Article 7(2).*

Or. en

Amendment 124

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

1. The Commission is empowered to adopt delegated acts in accordance with Article 73, ***after ensuring adequate consultation with relevant stakeholders***, to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:

Or. en

Amendment 125

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact ***posed by the high-risk AI systems already referred to in Annex III.***

Amendment

(b) the AI systems pose a ***serious*** risk of harm to the health and safety, or a ***serious*** risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact.

Or. en

Amendment 126
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(a a) the general capabilities and functionalities of the AI system independent of its intended purpose;

Or. en

Amendment 127
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(b a) the extent to which the AI system acts with a certain level of autonomy;

Or. en

Amendment 128
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

Amendment

(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system ***with a distinction to be made between an AI system used in an advisory capacity or one used directly to make a decision***, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

Or. en

Amendment 129
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 130
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

(g) the extent to which the outcome produced with an AI system is ***not*** easily reversible ***or remedied***, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;

Or. en

Amendment 131

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) the extent of the availability and use of demonstrated technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;

Or. en

Amendment 132

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g b (new)

Text proposed by the Commission

Amendment

(g b) the extent of human oversight and the possibility for a human to intercede in order to override a decision or recommendations that may lead to potential harm;

Or. en

Amendment 133

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g c (new)

Text proposed by the Commission

Amendment

(g c) the magnitude and likelihood of benefit of the deployment of the AI system for industry, individuals, or society at large;

Amendment 134

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g d (new)

Text proposed by the Commission

Amendment

(g d) the reticence risk and/or opportunity costs of not using the AI system for industry, individuals, or society at large;

Or. en

Amendment 135

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g e (new)

Text proposed by the Commission

Amendment

(g e) the amount and nature of data processed;

Or. en

Amendment 136

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 – point g f (new)

Text proposed by the Commission

Amendment

(g f) the benefits provided by the use of the AI system, including making products safer;

Or. en

Amendment 137

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 7 – paragraph 2 – point h – introductory part

Text proposed by the Commission

(h) the extent to which existing Union legislation provides for:

Amendment

(h) the extent to which existing Union legislation, ***in particular GDPR***, provides for:

Or. en

Amendment 138

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The Commission may remove AI systems from the list in Annex III if the conditions referred to in paragraph 1 are no longer met.

Or. en

Amendment 139

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 7 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. The Board, notified bodies and other actors may request the Commission to reassess an AI system. The AI system shall then be reviewed for reassessment and may be re-categorized. The Commission shall give reasons for its decision and publish the reasons. The details of the application procedure shall be laid down by the Commission by means of delegated acts in accordance with Article 73.

Amendment 140

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. High-risk AI systems shall comply with the *essential* requirements established in this Chapter, *taking into account the generally acknowledged state of the art, including as reflected in relevant industry and harmonised standards.*

Or. en

Amendment 141

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

- 2 a. AI systems referred to in Article 6 may be wholly or partially exempted from fulfilling the requirements referred to in Articles 8-15 if risks posed by the AI systems are sufficiently eliminated or mitigated through appropriate operational countermeasures or built-in fail-safe systems.*

Or. en

Amendment 142

Axel Voss, Deirdre Clune, Eva Maydell

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 ***if this system poses a risk of harm to health and safety or a risk of adverse impacts on fundamental rights.***

Or. en

Amendment 143

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – introductory part

Text proposed by the Commission

2. The risk management system shall consist of a continuous iterative process run throughout the entire ***lifecycle*** of a high-risk AI system, requiring regular ***systematic updating***. It shall comprise the following steps:

Amendment

2. The risk management system shall consist of a continuous iterative process run throughout the entire ***lifetime*** of a high-risk AI system, requiring regular ***review of the suitability of the risk management process to ensure its continuing effectiveness, and documentation of any decisions and actions taken.*** It shall comprise the following steps ***and all of these steps shall be integrated into already existing risk management procedures relating to the relevant Union sectoral legislation to avoid unnecessary bureaucracy:***

Or. en

Amendment 144

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

- (a) identification and analysis of the known and foreseeable risks ***associated***

Amendment

- (a) identification and analysis of the known and ***reasonable*** foreseeable risks ***of***

with each high-risk AI system;

harms most likely to occur to the health, safety or fundamental rights in view of the intended purpose of the high-risk AI system;

Or. en

Amendment 145

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

deleted

Or. en

Amendment 146

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(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;

(c) evaluation of *new risks consistent with those described in paragraph (2a) of this Article and identified* based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Or. en

Amendment 147

Axel Voss, Deirdre Clune, Eva Maydell

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 identified known and foreseeable risks to health and safety or fundamental rights***, in accordance with the provisions of the following paragraphs.

Or. en

Amendment 148

Axel Voss, Deirdre Clune, Eva Maydell

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 treating risks effectively while ensuring an appropriate and proportionate implementation of the requirements***. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards.

Or. en

Amendment 149

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any ***residual risk associated with each hazard as well as the overall***

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any ***significant*** residual risk of the high-risk AI systems is ***reasonably***

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.

judged *to be* acceptable, *having regards to the benefits that the high-risk AI system is reasonably expected to deliver and* provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. **Significant** residual risks shall be communicated to the user.

Or. en

Amendment 150

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – introductory part

Text proposed by the Commission

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

Amendment

In identifying the most appropriate risk management measures, the following shall be **taken into account**:

Or. en

Amendment 151

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) **elimination or** reduction of risks as far as possible through adequate design and development;

Amendment

(a) reduction of **identified and evaluated** risks as far as **proportionate and technologically possible in light of the generally acknowledged state of the art and industry standards**, through adequate design and development **of the high risk AI system in question**;

Or. en

Amendment 152

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, ***in particular as 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*** adequate information pursuant to Article 13 of this Article, and, where appropriate, training to users.

Or. en

Amendment 153

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

In ***eliminating or reducing*** risks related to the use of the high-risk AI system, due consideration ***shall be given to*** the technical knowledge, experience, education, training ***to be expected by*** the user ***and*** the environment in which the system is intended to be used.

Amendment

In ***seeking to reduce*** risks related to the use of the high-risk AI system, ***providers shall take into*** due consideration the technical knowledge, experience, education, training the user ***may need, including in relation to*** the environment in which the system is intended to be used.

Or. en

Amendment 154

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be ***tested*** for the purposes of identifying the most appropriate risk management measures. ***Testing*** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out

Amendment

5. High-risk AI systems shall be ***evaluated*** for the purposes of identifying the most appropriate ***and targeted*** risk management measures ***and weighing any such measures against the potential benefits and intended goals of the system.*** ***Evaluations*** shall ensure that high-risk AI systems perform consistently for their

in this Chapter.

intended purpose and they are in compliance with the **relevant** requirements set out in this Chapter.

Or. en

Amendment 155

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 6

Text proposed by the Commission

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system ***and do not need to go beyond what is necessary to achieve that purpose.***

Amendment

6. ***Evaluation or*** testing procedures shall be suitable to achieve the intended purpose of the AI system.

Or. en

Amendment 156

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***preliminarily*** defined metrics ***and*** probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***prior*** defined metrics, ***such as*** probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Or. en

Amendment 157

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 8

Text proposed by the Commission

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration ***shall be given*** to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, ***shall give*** specific consideration to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Or. en

Amendment 158

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 9

Text proposed by the Commission

9. For ***credit institutions regulated by Directive 2013/36/EU***, the aspects described in paragraphs 1 to 8 shall be ***part of*** the risk ***management*** procedures established by ***those institutions pursuant to Article 74 of that Directive***.

Amendment

9. For ***AI systems already covered by Union law that require them to carry out specific risk assessments***, the aspects described in paragraphs 1 to 8 shall be ***combined with*** the risk ***assessment*** procedures established by ***that Union law or deemed to be covered as part of it***.

Or. en

Amendment 159

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed ***on the basis of*** training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be, ***as far this can be reasonably expected and is feasible from a technical point of view***, developed ***with the best efforts to ensure*** training, validation and testing data sets that meet

the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 160

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern *in particular*,

Amendment

2. Training, ***machine-learning*** validation and testing data sets shall be subject to appropriate data governance and management practices ***during the expected lifetime***. Those practices shall concern, ***where relevant***:

Or. en

Amendment 161

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

(a) the ***relevant*** design choices;

Amendment

(a) the design choices ***for training and machine learning validation***;

Or. en

Amendment 162

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point b

Text proposed by the Commission

(b) data collection;

Amendment

(b) data collection ***processes***;

Or. en

Amendment 163

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) ***relevant*** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment

(c) data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Or. en

Amendment 164

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point e

Text proposed by the Commission

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

Amendment

deleted

Or. en

Amendment 165

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible ***unfair*** biases ***that are likely to affect the health and safety of persons or lead to discrimination prohibited under Union law;***

Or. en

Amendment 166

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of ***any possible*** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of ***significant and consequential*** data gaps or shortcomings, and how those gaps and shortcomings can be addressed;

Or. en

Amendment 167

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) the presumable context of the use as well as the intended purpose of the AI System.

Or. en

Amendment 168

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

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.*** These characteristics ***of the data sets*** may be met at the level of individual data

3. ***High Risk AI systems should be designed and developed with the best efforts to ensure that, where appropriate, training datasets, machine-learning validation and testing data sets are sufficiently accurate,*** relevant ***and representative in view of the intended purpose of the*** AI system. These characteristics may be met at the level of individual data sets or a combination

sets or a combination thereof.

thereof.

Or. en

Amendment 169

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In assessing the quality of a data set, account shall be taken to the extent to which the data set is constructed with a view to fulfilling in particular the following aspects:

a) provides a similar output for relevant demographic Groups impacted by the system;

b) minimizes disparities in outcomes for relevant demographic groups impacted by the system, in case where the system allocates resources or opportunities to natural persons;

c) minimizes the potential for stereotyping, demeaning, or erasing relevant demographic groups impacted by the system where the system describes, depicts, or otherwise represents people, cultures, or society.

Or. en

Amendment 170

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

Amendment

4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose,

deleted

the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 171
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The processing of personal data to train, validate and test data sets of an AI system in order to meet the requirements of this Regulation shall be lawful for the purpose of the legitimate interest of the provider as referred to in Article 6(1f) GDPR or in accordance with Article 6(4) GDPR subject to appropriate safeguards in line with Article 89 GDPR for ensuring to the extent necessary and proportionate one or more of the following objectives:

- a) national and common security;***
- b) functioning of the internal market;***
- c) prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;***
- d) exercise of public authorities' official mission, such as tax and customs authorities, financial investigation units, independent administrative authorities, or financial market authorities responsible for the regulation and supervision of securities markets should not be regarded as recipients if they process personal data to train, validate and test an AI system which are necessary to carry out a particular inquiry in the general interest,***

in accordance with Union or Member State law;

e) network and information security to the extent necessary and proportionate for this purpose;

f) protection of an interest which is essential for the life of the data subject or that of another natural person, in particular where it is necessary for reasons of public interest in the areas of public health.

Or. en

Amendment 172
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission

5. To the extent that it is ***strictly*** necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems ***may*** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including ***technical limitations on the re-use and use of*** state-of-the-art security and privacy-preserving measures, such as pseudonymisation, ***or*** encryption where anonymisation may significantly affect the purpose pursued.

Amendment

5. To the extent that it is necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems ***will have a legal basis and necessary exception to*** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including:

(i) state-of-the-art security and privacy-preserving measures, such as ***data-minimization***, pseudonymisation, encryption, ***and*** where anonymisation may significantly affect the purpose pursued;

(ii) measures ensuring availability and resilience of processing systems and services, and the ability to restore the availability and access to special category personal data in a timely manner in the event of a physical or technical incident;

(iii) processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing;

(iv) measures for user identification, authorisation, protection of data during transmission, protection of data during storage, ensuring physical security of locations at which personal data are processed, internal IT and IT security governance and management, certification/assurance of processes and products;

(v) measures for ensuring data minimisation, data quality, limited data retention, and data portability and ensuring erasure.

Or. en

Amendment 173

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. Providers and user may comply with the obligations set out in this Article through the use of third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices.

Or. en

Amendment 174
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 175
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

1. The technical documentation of a high-risk AI system shall be drawn up, ***where possible, relevant, and without compromising intellectual property rights or trade secrets,*** before that system is placed on the market or put into service and shall be kept up-to date.

Or. en

Amendment 176
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that

The technical documentation shall be drawn up, ***where possible, relevant, and***

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.

without compromising intellectual property rights or trade secrets, in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV ***or in the case of SME's and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority.***

Or. en

Amendment 177

Axel Voss, Deirdre Clune, Eva Maydell

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 ***only one single and appropriate*** technical documentation shall be drawn up ***for each product***, containing all the information set out in Annex IV as well as the information required under those legal acts.

Or. en

Amendment 178

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. To ensure that a single technical documentation is possible, terms and

definitions related to this required documentation and any required documentation in the appropriate Union sectoral legislation shall be aligned as much as possible;

Or. en

Amendment 179

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall *be designed and developed with capabilities enabling* the automatic recording of events ('logs') *while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.*

Amendment

1. High-risk AI systems shall *technically allow* the automatic recording of events ('logs') *over the durations of the lifetime of the system.*

Or. en

Amendment 180

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. *The logging capabilities shall* ensure a level of traceability of the AI system's functioning *throughout its lifecycle that* is appropriate to the intended purpose of the system.

Amendment

2. *In order to* ensure a level of traceability of the AI system's functioning *which* is appropriate to the intended purpose of the system, *the logging capabilities shall enable the recording of events relevant for the identification of situations that may:*

(i) result in the AI system presenting a risk within the meaning of Article 65 (1);
or

(ii) lead to a substantial modification that facilitates the post market monitoring

referred to in Article 61.

Or. en

Amendment 181

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 3

Text proposed by the Commission

Amendment

3. *In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-market monitoring referred to in Article 61.* ***deleted***

Or. en

Amendment 182

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

Amendment

4. *For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:* ***deleted***

(a) *recording of the period of each use of the system (start date and time and end date and time of each use);*

(b) *the reference database against which input data has been checked by the system;*

(c) *the input data for which the search has led to a match;*

(d) *the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).*

Or. en

Amendment 183

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to *interpret* the system's *output and use it appropriately*. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in *Chapter 3* of this Title.

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to *reasonably understand* the system's *functioning*. An appropriate type and degree of transparency shall be ensured, *depending on the intended purpose of the system*, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in *Article 16 and Article 29* of this Title. *The explanation shall be provided at least in the language of the country where the AI system is deployed.*

Transparency shall thereby mean that, to the extent that can be reasonably expected and is feasible in technical terms at the time when the AI system is placed on the market, the AI system is interpretable to the provider, in that the provider can understand the rationale of decisions taken by the high risk AI system, while enabling the user to understand and use the AI system appropriately, by generally knowing how the AI system works and what data it processes.

Or. en

Amendment 184

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, **complete**, correct and clear information that **is** relevant, accessible and comprehensible to users.

Amendment

2. High-risk AI systems shall be accompanied by **comprehensible** instructions for use in an appropriate digital format or **made** otherwise **available** that include concise, correct and clear information that **helps supporting informed decision-making by users and is reasonably** relevant, accessible and comprehensible to users.

Or. en

Amendment 185
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 13 – paragraph 3 – introductory part

Text proposed by the Commission

3. The information referred to in paragraph 2 shall specify:

Amendment

3. **To the extent necessary to achieve the outcomes referred to in paragraph 1,** the information referred to in paragraph 2 shall specify:

Or. en

Amendment 186
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

(a) the identity and the contact details of the provider **and**, where applicable, of **its** authorised representative;

Amendment

(a) the identity and the contact details of the provider, where applicable, of **their** authorised representative;

Or. en

Amendment 187

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – introductory part

Text proposed by the Commission

(b) the ***characteristics***, capabilities and limitations of performance of the high-risk AI system, including:

Amendment

(b) the capabilities and limitations of performance of the high-risk AI system ***that are relevant to the material risks associated with the intended purpose, including where appropriate:***

Or. en

Amendment 188

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Amendment

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity, ***including an overview of the capabilities and performance metrics of the AI system, and of representative use cases based on the intended purpose;***

Or. en

Amendment 189

Axel Voss, Deirdre Clune, Eva Maydell

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) **the** known or foreseeable **circumstances**, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights, **including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used;**

Or. en

Amendment 190

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – point v

Text proposed by the Commission

(v) **when appropriate, specifications for the** input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.

Amendment

(v) **relevant information about user actions that may influence system performance, including type or quality of** input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.

Or. en

Amendment 191

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) a description of the mechanisms included within the AI system that allow users to properly collect, store and interpret the logs in accordance with Art

12(1), where relevant.

Or. en

Amendment 192

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they *can be effectively overseen* by natural persons during the *period in which* the AI system *is in use*.

Amendment

1. *Where proportionate to the risks associated with the high-risk system and where technical safeguards are not sufficient*, high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they *allow informed oversight* by natural persons during the *expected lifetime of the device. Oversight capabilities should be tailored to the AI system's intended purpose and the context of use and take into account cases where human oversight may compromise the correct and safe functioning of* the AI system.

Or. en

Amendment 193

Axel Voss, Deirdre Clune, Eva Maydell

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

Amendment

2. Human oversight shall aim at preventing or minimising *known and reasonably foreseeable as well as unacceptable* risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose, in particular when such risks persist notwithstanding the application of other requirements set out in

this Chapter.

this Chapter. ***Human oversight requirements shall only apply when appropriate, proportionate and justified by a proven added value to the protection of health, safety and fundamental rights.***

Or. en

Amendment 194

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

3. Human oversight shall be ensured through either one or all of the following measures:

Amendment

3. ***The degree of*** human oversight ***shall be adapted to the specific risks, the level of automation, and context of the AI system and*** shall be ensured through either one or all of the following ***types of*** measures:

Or. en

Amendment 195

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point a

Text proposed by the Commission

(a) identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;

Amendment

(a) identified and built, when technically feasible ***and appropriate***, into the high-risk AI system by the provider before it is placed on the market or put into service;

Or. en

Amendment 196

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b

Text proposed by the Commission

(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user.

Amendment

(b) identified by the provider ***operationalized*** before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user;

Or. en

Amendment 197

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) required of the user, if appropriate, for their implementation;

Or. en

Amendment 198

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b b (new)

Text proposed by the Commission

Amendment

(b b) included during the development, testing, or monitoring processes.

Or. en

Amendment 199

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. ***The measures referred to in paragraph 3 shall enable the individuals***

4. ***For the purpose of implementing paragraphs 1 to 3, the high-risk AI system***

to whom human oversight is assigned **to** do the following, as appropriate to the circumstances:

shall ***be provided to the user in such a way that natural persons*** to whom human oversight is assigned **can** do the following, as appropriate ***and proportionate*** to the circumstances ***and instructions for use and in accordance with industry standards***:

Or. en

Amendment 200

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point a

Text proposed by the Commission

(a) ***fully*** understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Amendment

(a) ***to be aware and sufficiently*** understand the ***relevant*** capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Or. en

Amendment 201

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), ***in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons***;

Amendment

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias');

Or. en

Amendment 202
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 14 – paragraph 4 – point c

Text proposed by the Commission

(c) be able to correctly interpret the high-risk AI system’s output, taking into account ***in particular the characteristics of the system and*** the interpretation tools and methods available;

Amendment

(c) be able to correctly interpret the high-risk AI system’s output, taking into account, ***for example***, the interpretation tools and methods available;

Or. en

Amendment 203
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 14 – paragraph 4 – point e

Text proposed by the Commission

(e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure.

Amendment

(e) be able to intervene on the operation of the high-risk AI system or interrupt, ***where reasonable and technically feasible***, the system through a “stop” button or a similar procedure, ***except if the human interference increases the risk or would negatively impact the performance in consideration of generally acknowledge state-of-the-art.***

Or. en

Amendment 204
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as

Amendment

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as

to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.

to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been *separately* verified and confirmed by at least two natural persons *on-site or remotely, except for temporary actions or decisions which cannot be delayed due to safety or security reasons for the purpose of law enforcement.*

Or. en

Amendment 205

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. For the purpose of implementing paragraph 2, in the case where the result of an identification is inconclusive, the human oversight requirements from paragraphs 3 to 5 shall be performed directly internally by the closest entity to the user in the supply chain of the high-risk AI system.

Or. en

Amendment 206

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. With the exception of high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall not be interpreted as requiring a human to review every action or decision taken by the AI system. Full automation of such systems shall be possible provided that technical measures are put in place to

comply with provisions in paragraphs 1 to 4.

Or. en

Amendment 207

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their *lifecycle*.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose *and to the extent that can be reasonably expected and is in accordance with relevant industry standards*, an appropriate level of accuracy, *reliability*, robustness and cybersecurity, and *the basic pillars of information security and protection, such as confidentiality, integrity and availability as well as to* perform consistently in those respects throughout their *lifetime while taking their evolving nature into account*.

Or. en

Amendment 208

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. To address the technical aspects of how to measure the appropriate levels of accuracy and robustness in paragraph 1, the European Artificial Intelligence Board shall bring together national metrology and benchmarking authorities and provide non-binding guidance on the matter as per Article 56(2a) of this

Amendment 209

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 2

Text proposed by the Commission

2. The *levels of accuracy* and the *relevant accuracy metrics of high-risk AI systems* shall be declared in the accompanying instructions of use.

Amendment

2. The *range of expected performance* and the *operational factors that affect that performance*, shall be declared, *where possible*, in the accompanying instructions of use.

Or. en

Amendment 210

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be *resilient* as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be *designed and developed with safety and security by design mechanism by default so that they achieve, in the light of their intended purpose, an appropriate level of cyber resilience* as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 211

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.

Amendment

The robustness of high-risk AI systems may be achieved through ***diverse*** technical redundancy solutions, which may include ***reasonably designed*** backup or fail-safe plans ***by the appropriate provider or user or as mutually agreed by the provider and the user.***

Or. en

Amendment 212

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

High-risk AI systems that continue to learn after being placed on the market or put into 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.

Or. en

Amendment 213

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In accordance with Article 42 (2), the compliance with Article 15 for high-risk AI systems that have already been certified or for which a statement of conformity has been issued under a

cybersecurity scheme pursuant to Regulation (EU) 2019/881 shall be assumed.

Or. en

Amendment 214

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The technical solutions *aimed at ensuring* the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Amendment

The technical solutions *and organisational measures designed to uphold* the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Or. en

Amendment 215

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission

The technical solutions *to address AI specific vulnerabilities shall* include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Amendment

The technical solutions *may* include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws, *or exploratory attacks that may aim to extract knowledge, algorithms, trade secrets or training information from the AI.*

Or. en

Amendment 216

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

Amendment

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title *before placing them on the market or putting them into service*;

Or. en

Amendment 217
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(a a) indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;

Or. en

Amendment 218
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(c) *draw-up the technical* documentation *of the high-risk AI system*;

(c) *keep the* documentation *referred to in Article 18*;

Or. en

Amendment 219
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

(d) when under their control, keep the logs automatically generated by their high-risk AI systems;

Amendment

(d) when under their control, keep the logs automatically generated by their high-risk AI systems, ***in accordance with Article 20;***

Or. en

Amendment 220

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ***ensure that the high-risk AI system undergoes*** the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ***carry out*** the relevant conformity assessment procedure, ***as provided for in Article 19,*** prior to its placing on the market or putting into service;

Or. en

Amendment 221

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Amendment

(g) take the necessary corrective actions ***as referred to in Art 21,*** if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 222

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point i

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 223

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point j

Text proposed by the Commission

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

Amendment

- (j) upon **reasoned** request of a national competent authority, **provide the relevant information and documentation to** demonstrate the conformity of the high-risk AI system.

Or. en

Amendment 224

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. **That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:**

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation **and that shall be incorporated as part of an existing quality management system under sectoral legislation or as provided by the International Organisation for Standardization.**

Or. en

Amendment 225

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;

deleted

Or. en

Amendment 226

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;

deleted

Or. en

Amendment 227

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

deleted

Or. en

Amendment 228

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;

deleted

Or. en

Amendment 229

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point e

Text proposed by the Commission

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

deleted

Or. en

Amendment 230

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage,

deleted

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;

Or. en

Amendment 231

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point g

Text proposed by the Commission

Amendment

(g) *the risk management system referred to in Article 9;* *deleted*

Or. en

Amendment 232

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point h

Text proposed by the Commission

Amendment

(h) *the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;* *deleted*

Or. en

Amendment 233

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point i

Text proposed by the Commission

Amendment

(i) *procedures related to the reporting of serious incidents and of* *deleted*

*malfunctioning in accordance with
Article 62;*

Or. en

Amendment 234

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point j

Text proposed by the Commission

Amendment

(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;* *deleted*

Or. en

Amendment 235

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point k

Text proposed by the Commission

Amendment

(k) *systems and procedures for record keeping of all relevant documentation and information;* *deleted*

Or. en

Amendment 236

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point l

Text proposed by the Commission

Amendment

(l) *resource management, including security of supply related measures;* *deleted*

Amendment 237

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 17 – paragraph 1 – point m***Text proposed by the Commission**Amendment*

(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.

deleted

Or. en

Amendment 238

Axel Voss, Deirdre Clune, Eva Maydell

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 documen-tation referred to in Article 11 in accordance with Annex IV.*

1. *The provider shall, for a period of 3 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:*

(a) the technical documentation referred to in Article 11 and Annex IV;

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

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

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

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

Amendment 239

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 20 – paragraph 1***Text proposed by the Commission*

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

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by *law as well as under their factual control and to the extent that it is technically feasible. They shall keep them* for a period *of at least six months, unless provided otherwise in* applicable Union or national law.

Or. en

Amendment 240

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 21 – paragraph 1***Text proposed by the Commission*

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Amendment

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately, *where applicable, investigate the causes in collaboration with the user and,* take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Amendment 241

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 22 – paragraph 1***Text proposed by the Commission*

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the ***national competent*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

Amendment

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the ***market surveillance*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular ***the nature*** of the non-compliance and of any ***relevant*** corrective actions taken ***by the provider***.

Or. en

Amendment 242

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 23 – paragraph 1***Text proposed by the Commission*

Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in ***an official Union language determined by the Member State concerned***. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-

Amendment

Providers of high-risk AI systems shall, upon ***a reasoned*** request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in ***a language that can be easily understood by that national competent authority***. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-

risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. ***Any information submitted in accordance with the provision of this article shall be considered by the national competent authority a trade secret of the company that is submitting such information and kept strictly confidential.***

Or. en

Amendment 243

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 23 a (new)

Text proposed by the Commission

Amendment

Article 23 a

Clarification of responsibilities along the AI value chain

1. Concerning high risk AI systems, any natural or legal person shall be considered a new provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

(a) they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;

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

(c) they modify the intended purpose of a non high-risk AI system already placed on the market or put into service, in a way which makes the modified system a high-

risk AI System;

(d) they adapt a general purpose AI system system, already placed on the market or put into service, to a specific intended purpose.

2 . Where the circumstances referred to in paragraphs 1(a), (b) and (c) occur, the former provider shall no longer be considered a provider for the purposes of this Regulation. The former provider shall upon request and without compromising its own intellectual property rights or trade secrets, provide the new provider with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

3. The original provider of a general purpose AI system shall, without compromising its own intellectual property rights or trade secrets and to the extent appropriate and feasible:

(a) ensure that the general purpose AI system which may be used as high-risk AI system complies with the requirements established in Article 9, 10, 11, 13(2)/(3) and 15 of this Regulation;

(b) comply with the obligations set out in Art 16aa, 16e, 16f, 16g, 16i, 16j, 48 and 61 of this Regulation;

(c) assess the reasonable foreseeable misuses of the general purpose AI system that may arise during the expected lifetime and install mitigation measures against those cases based on the generally acknowledged state of the art;

(d) provide the new provider referred to in paragraph 1(d) with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

4. For high-risk AI systems that are safety components of products to which the legal

acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations referred to in Article 16 under either of the following scenarios:

(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer; or

(ii) the high-risk AI system is put into service under the name or trademark of the product manufacturer after the product has been placed on the market.

5. Third parties involved in the sale and the supply of software including general purpose application programming interfaces (API), software tools and components, providers who develop and train AI systems on behalf of a deploying company in accordance with their instruction, or providers of network services shall not be considered providers for the purposes of this Regulation.

Or. en

Amendment 244

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 24

Text proposed by the Commission

Amendment

Article 24

deleted

Obligations of product manufacturers

Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the

product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.

Or. en

Amendment 245

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 1

Text proposed by the Commission

1. Prior to making their systems available on the Union market, ***where an importer cannot be identified***, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Amendment

1. Prior to making their systems available on the Union market, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Or. en

Amendment 246

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – introductory part

Text proposed by the Commission

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:

Amendment

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***For the purpose of this Regulation***, the mandate shall empower the authorised representative to carry out ***only*** the following tasks:

Or. en

Amendment 247

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point a

Text proposed by the Commission

(a) ***keep a copy of*** the EU declaration of conformity and the technical documentation ***at the disposal of the national competent authorities and national authorities referred to in Article 63(7);***

Amendment

(a) ***ensure that*** the EU declaration of conformity and the technical documentation ***have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;***

Or. en

Amendment 248

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), for a period ending 3 years after the high-risk AI system has been placed on the market or put into service, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;

Or. en

Amendment 249

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) cooperate with ***competent*** national authorities, upon a reasoned request, on

(c) cooperate with national ***supervisory*** authorities, upon a reasoned request, on

any action the latter takes in relation to the high-risk AI system.

any action the latter takes in relation to the high-risk AI system;

Or. en

Amendment 250

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 251

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the market surveillance authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof.

Or. en

Amendment 252

Axel Voss, Deirdre Clune, Eva Maydell

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 system shall ensure that:

Amendment

1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by ensuring that:***

Or. en

Amendment 253

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point a

Text proposed by the Commission

- (a) the ***appropriate*** conformity assessment procedure has been carried out by the provider of that AI system

Amendment

- (a) the ***relevant*** conformity assessment procedure ***referred to in Article 43*** has been carried out by the provider of that AI system;

Or. en

Amendment 254

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point c

Text proposed by the Commission

- (c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.

Amendment

- (c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use;

Or. en

Amendment 255

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(c a) the authorised representative referred to in Article 25 has been established by the Provider.

Or. en

Amendment 256
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission

Amendment

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, ***or is falsified, or accompanied by falsified documentation*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

Or. en

Amendment 257
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 26 – paragraph 4

Text proposed by the Commission

Amendment

4. Importers shall ***ensure that, while a high-risk AI system is under their responsibility***, where applicable, ***storage or transport conditions do not jeopardise its***

4. Importers shall ***keep, for a period ending 3 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by***

compliance with the requirements set out in Chapter 2 of this Title.

the notified body, where applicable, of the instructions for use and of the EU declaration of conformity.

Or. en

Amendment 258

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 259

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

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

Amendment 260

Axel Voss, Deirdre Clune, Eva Maydell

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 Article 16 and Article 26(3), respectively*.

Or. en

Amendment 261

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 27 – paragraph 2***Text proposed by the Commission*

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

Amendment

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

Amendment 262**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 27 – paragraph 4***Text proposed by the Commission*

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

Amendment

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

Or. en

Amendment 263**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 27 – paragraph 5***Text proposed by the Commission*

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that

Amendment

5. Upon a reasoned request from a national competent authority ***and where no authorised representative has been***

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.*

appointed, distributors of high-risk AI systems shall provide that authority with all the information and documentation *regarding its activities as described in paragraphs 1 to 4.*

Or. en

Amendment 264

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 27 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 265

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 28

Text proposed by the Commission

Amendment

Article 28

deleted

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

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

(a) they place on the market or put into service a high-risk AI system under

their name or trademark;

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

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

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

Or. en

Amendment 266

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 267

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 268

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 269

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 3

Text proposed by the Commission

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

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

system.

purpose of the high-risk AI system.

Or. en

Amendment 270

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 4 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 271

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 5 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 272

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 273

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. The provider shall be obliged to cooperate closely with the user and in particular provide the user with the necessary information to allow the

fulfilment of the obligations set out in this Article.

Or. en

Amendment 274

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 29 – paragraph 6 b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 275

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 31 – paragraph 2

Text proposed by the Commission

Amendment

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules **and the artificial intelligence technologies** for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.

Or. en

Amendment 276

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 32 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 277

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 32 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 278

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 33 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

Amendment 279

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 33 – paragraph 10

Text proposed by the Commission

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

Amendment

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

Amendment 280

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 34 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Amendment 281

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 38 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 282

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 39 – paragraph 1

Text proposed by the Commission

Amendment

Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified Bodies under this Regulation.

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

Or. en

Amendment 283

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 39 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 284

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 39 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

3. In addition, where conformity assessment bodies established under the law of a third country have not been accredited by signatory bodies of such international accreditation or conformity assessment schemes, third-country conformity assessment bodies may carry out the activities of Notified Bodies where international mutual recognition arrangements, conformity assessment protocols, or other agreements exist between the EU and the country in which the conformity assessment body is established.

Or. en

Amendment 285

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 40 – paragraph 1

Text proposed by the Commission

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

Amendment

1. High-risk AI systems which are in conformity with harmonised standards ***developed in accordance with Regulation 1025/2021*** or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.

Or. en

Amendment 286

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 40 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

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

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

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

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

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

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

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

Or. en

Amendment 287

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 40 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 288

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 41 – paragraph 1

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).

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

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

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

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

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

Or. en

Amendment 289

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 41 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 290
Axel Voss, Deirdre Clune, Eva Maydell

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 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.

Amendment

3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements, ***and as long as those requirements are not covered by harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.***

Or. en

Amendment 291
Axel Voss, Deirdre Clune, Eva Maydell

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

Or. en

Amendment 292

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 42 – paragraph 1

Text proposed by the Commission

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

Amendment

1. High-risk AI systems that have been trained and tested on data **reflecting** the specific geographical, behavioural and functional setting within which they are intended to be used shall be presumed to be in compliance with the **respective requirements** set out in Article 10(4).

Or. en

Amendment 293

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 42 – paragraph 2

Text proposed by the Commission

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme **pursuant to** Regulation (EU) 2019/881 of the European Parliament and of the Council⁶³ and the references of which have been published in

Amendment

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme to Regulation (EU) 2019/881 of the European Parliament and of the Council⁶³ **or pursuant to other harmonization legislation in the field of**

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.

security of network and information systems and electronic communications networks and services and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

⁶³ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

⁶³ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

Or. en

Amendment 294

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 295

Axel Voss, Deirdre Clune, Eva Maydell

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**

Or. en

Amendment 296

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 297

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 2

Text proposed by the Commission

2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the

Amendment

2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the

market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.

market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment ***based on internal control*** shall be ***verified by means of an ex-post assessment and*** carried out as part of the procedure referred to in Articles 97 to 101 of that Directive ***but only to the extent that prudential risks and related requirements are concerned.***

Or. en

Amendment 298

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 3 – introductory part

Text proposed by the Commission

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

Amendment

3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, ***and which are subject to points 1 and 2 of Article 6*** the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.

Or. en

Amendment 299

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 4 – introductory part

Text proposed by the Commission

4. High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system

Amendment

4. High-risk AI systems, ***that have already been subject to a conformity assessment procedure,*** shall undergo a new conformity assessment procedure ***in***

is intended to be further distributed or continues to be used by the current user.

line with the provisions foreseen by the legal acts listed in Annex II, section A, whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.

Or. en

Amendment 300

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 301

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 43 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 302
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 43 – paragraph 5

Text proposed by the Commission

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

Amendment

5. ***After consulting the AI Board referred to in Article 56 and after providing substantial evidence, followed by thorough consultation and the involvement of the affected stakeholders.*** The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII in order to **amend** elements of the conformity assessment procedures that become necessary **or unnecessary** in light of technical progress.

Or. en

Amendment 303
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 43 – paragraph 6

Text proposed by the Commission

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

Amendment

6. ***After consulting the AI Board referred to in Article 56 and after providing substantial evidence, followed by thorough consultation and the involvement of the affected stakeholders,*** The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or

among notified bodies.

minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.

Or. en

Amendment 304

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 46 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 305

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 47 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

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

stopped with immediate effect.

Or. en

Amendment 306

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 47 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 307

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 48 – paragraph 1

Text proposed by the Commission

1. The provider shall draw up a written EU declaration of conformity for each AI system and keep it at the disposal

Amendment

1. The provider shall draw up a written *or electronically signed* EU declaration of conformity for each AI

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.

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

Or. en

Amendment 308

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 48 – paragraph 5

Text proposed by the Commission

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce elements that become necessary in light of technical progress.

Amendment

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

Or. en

Amendment 309

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 49 – paragraph 1

Text proposed by the Commission

1. The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying

Amendment

1. The *physical* CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as

documentation, as appropriate.

appropriate.

Or. en

Amendment 310

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 49 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. An electronic CE marking may replace the physical marking if it can be accessed via the display of the product or via a machine-readable code.

Or. en

Amendment 311

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 50

Text proposed by the Commission

Amendment

Article 50

deleted

Document retention

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

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

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

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

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

applicable;

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

Or. en

Amendment 312

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 51 – paragraph 1

Text proposed by the Commission

Before placing on the market or putting into service a high-risk AI system ***referred to in Article 6(2)***, the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

Amendment

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

Or. en

Amendment 313

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 52 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Providers shall ensure that AI systems intended to ***directly*** interact with natural persons are designed and developed in such a way that ***the AI system, the provider itself or the user can inform the natural person exposed to an AI system*** that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. ***Where relevant, this information shall also include which functions are AI enabled, if there is human oversight and who is responsible for the decision-making process.*** This obligation shall not apply to AI systems authorised by law to

detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.

Or. en

Amendment 314

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 52 – paragraph 3 – introductory part

Text proposed by the Commission

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

Amendment

3. Users of an AI system that generates or manipulates audio or ***visual*** content that would falsely appear to be authentic or truthful ***and which features depictions of people appearing to say or do things they did not say or do, without their consent*** ('deep fake'), shall disclose that the content has been artificially generated or manipulated. ***Disclosure shall mean labelling the content in a way that informs that the content is inauthentic and that is clearly visible for the recipient of that content. To label the content, users shall take into account the generally acknowledged state of the art and relevant harmonised standards and specifications.***

Or. en

Amendment 315

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 52 – paragraph 3 – subparagraph 1

Text proposed by the Commission

However, the first subparagraph shall not apply where the use ***is authorised*** by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to

Amendment

However, the first subparagraph shall not apply where the use ***of an AI system that generates or manipulates audio or visual content is authorized*** by law to detect, prevent, investigate and prosecute criminal

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.

offences *or where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video game visuals or analogous work* or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.

Or. en

Amendment 316

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 52 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 317

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 1

Text proposed by the Commission

Amendment

1. AI regulatory sandboxes ***established by one or more Member States competent authorities or the European Data Protection Supervisor shall*** provide a controlled environment that facilitates the development, testing and validation of innovative AI systems ***for a limited time*** before their placement on the market or putting into service pursuant to a specific

1. ***The competent authorities of the Member States shall establish several physical and digital*** AI regulatory sandboxes ***six months prior to the entry into application of this Regulation based on well-established criteria that*** provide a controlled environment that facilitates the development, testing and validation of innovative AI systems before their

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.

placement on the market or putting into service pursuant to a specific plan. ***SMEs, start-ups, enterprises, innovators or other relevant actors could be included as partners in the regulatory sandboxes.*** This shall take place under the direct supervision and guidance by the ***respective national*** competent authorities ***or by the European Data Protection Supervisor in relation to AI systems provided by the EU institutions, bodies and agencies*** with a view to ***identify risks to health and safety and fundamental rights, test mitigation measures for identified risks, demonstrate prevention of these risks and otherwise*** ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. ***The Commission shall play a complementary role, allowing those Member States with demonstrated experience with sandboxing to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes.***

Or. en

Amendment 318

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. This article shall also apply to AI systems for which full compliance with the requirements of Title III Chapter 2 requires an initial phase of placing the systems on the market or putting them into service and using the experiences gained in such initial phase to further develop the AI system so as to fully fulfil

the requirements of Title III Chapter 2, particularly for the case of general purpose AI Systems.

Or. en

Amendment 319

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 320

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

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

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

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

(c) improve legal certainty through cooperation with the authorities involved in the AI regulatory sandbox with a view

to ensuring compliance with this Regulation and, where appropriate, with other Union and Member States legislation;

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

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

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

Or. en

Amendment 321

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 53 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Member States ***in collaboration with the Commission*** shall ensure that to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national authorities are associated to the operation of the AI regulatory sandbox. ***As appropriate, national competent authorities may allow for the involvement***

in the AI regulatory sandbox of other actors within the AI ecosystem such as national or European standardisation organisations, notified bodies, testing and experimentation facilities, research and experimentation labs and innovation hubs.

Or. en

Amendment 322

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Access to the AI regulatory sandboxes and supervision and guidance by the relevant authorities shall be free of charge, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner. It shall be open to any provider or prospective provider of an AI system who fulfils national eligibility and selection criteria and who has been selected by the national competent authorities or by the European Data Protection Supervisor. Participation in the AI regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project in any case not longer than a maximum period of 2 years, starting upon the notification of the selection decision. The participation may be extended for up to 1 more year.

Or. en

Amendment 323

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 53 – paragraph 3

Text proposed by the Commission

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. ***Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.***

Amendment

3. ***The participation in*** the AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities ***supervising the sandbox. However, provided that the participant(s) respect the sandbox plan and the terms and conditions for their participation and follow in good faith the guidance given by the authorities, no administrative enforcement action shall be taken by the authorities for infringement of applicable Union or Member State legislation.***

Or. en

Amendment 324
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 53 – paragraph 4

Text proposed by the Commission

4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the experimentation taking place in the sandbox.

Amendment

4. Participants in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm ***intentionally*** inflicted on third parties as a result from the experimentation taking place in the sandbox, ***which was known or reasonably foreseeable at the time of experimentation and the risk of which the sandbox participants was not made aware of.***

Or. en

Amendment 325
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 53 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 326
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 53 – paragraph 5

Text proposed by the Commission

Amendment

5. Member States' competent authorities ***that have established*** AI regulatory sandboxes ***shall*** coordinate their activities ***and*** cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those ***scheme***, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.

5. Member States' competent authorities ***in collaboration with the Commission shall establish*** AI regulatory sandboxes, ***as much as possible through national and regional initiatives, in particular through European digital innovation hubs, and closely*** coordinate their activities ***as well as*** cooperate within the framework of the European Artificial Intelligence Board. They shall submit annual reports to the Board and the Commission on the results from the implementation of those ***schemes***, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox. ***The annual reports or abstracts shall be made available to the public, online, in order to further enable innovation within the***

Union. Outcomes and learnings of the sandbox should be leveraged when monitoring the effectiveness and enforcement of this Regulation and kept into account when proceeding to amending it. The annual reports shall also be submitted to the AI Board which shall publish on its website a summary of all good practices, lessons learnt and recommendations.

Or. en

Amendment 327

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 6

Text proposed by the Commission

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

Amendment

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts *in accordance with the Council's communication(11/2020) and in strong cooperation with relevant stakeholders*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

Amendment 328

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. *Notwithstanding the modalities and conditions outlined in paragraph 6, Member States shall design regulatory sandboxes to provide access to as many providers as possible. There shall be a particular focus on the use and application of general purpose AI systems. Member States may establish virtual sandboxing environments to ensure that sandboxes can meet the demand.*

Or. en

Amendment 329

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 53 – paragraph 6 b (new)

Text proposed by the Commission

Amendment

6 b. *The Commission shall establish an EU AI Regulatory Sandboxing Work Programme whose modalities referred to in Article 53(6) shall cover the elements set out in Annex IXa. The Commission shall proactively coordinate with national and local authorities, where relevant.*

Or. en

Amendment 330

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. In the AI regulatory sandbox personal data lawfully collected for other purposes *shall* be processed for the purposes of developing and testing certain

1. In the AI regulatory sandbox personal data lawfully collected for other purposes *may* be processed for the purposes of developing and testing certain

innovative AI systems in the sandbox
under the following conditions:

innovative AI systems in the sandbox
under the following conditions:

Or. en

Amendment 331

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point a – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 332

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point c

Text proposed by the Commission

(c) there are effective monitoring mechanisms to identify if any high risks to the ***fundamental*** rights of the data subjects may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing;

Amendment

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

Or. en

Amendment 333

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point e

Text proposed by the Commission

(e) any personal data processed are not be transmitted, transferred or otherwise accessed by other parties;

Amendment

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

Or. en

Amendment 334

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point f

Text proposed by the Commission

(f) any processing of personal data in the context of the sandbox ***do not lead to measures or decisions affecting*** the data subjects;

Amendment

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

Or. en

Amendment 335

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 54 – paragraph 1 – point g

Text proposed by the Commission

(g) any personal data processed in the context of the sandbox are deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

Amendment

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

Amendment 336
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 54 – paragraph 1 – point h

Text proposed by the Commission

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

Amendment

(h) the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox;

Or. en

Amendment 337
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 54 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Provided that the conditions of paragraph 1 are met, personal data processed for developing and testing innovative AI systems in the sandbox shall be considered compatible for the purposes of Article 6(4) GDPR

.

Or. en

Amendment 338
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – title

Text proposed by the Commission

Measures for *small-scale* providers and users

Amendment

Measures for providers and users *that are SME's or start-ups*

Or. en

Amendment 339
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – paragraph 1 – point a

Text proposed by the Commission

(a) provide *small-scale providers* and start-ups with priority access to *the* AI regulatory sandboxes to the extent that *they* fulfil the eligibility conditions;

Amendment

(a) provide *SMEs* and start-ups with priority access to *and make* AI regulatory sandboxes *reusable as well as affordable* to the extent that *SMEs and start-ups* fulfil the eligibility conditions;

Or. en

Amendment 340
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – paragraph 1 – point b

Text proposed by the Commission

(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of *the small-scale providers and users*;

Amendment

(b) organise specific awareness raising *and training* activities about the application of this Regulation tailored to the needs of *SME's and start-ups*;

Or. en

Amendment 341
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – paragraph 1 – point c

Text proposed by the Commission

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

Amendment

(c) where appropriate, establish a dedicated channel for communication with *SME's and start-ups* and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation;

Or. en

Amendment 342

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) consult representative organisations of SMEs and start ups and involve them in the development of relevant standards;

Or. en

Amendment 343

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 55 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) create development paths and services for SMEs and start ups, ensuring that government support is provided at all stages of their development, in particular by promoting digital tools and developing AI transition plans;

Or. en

Amendment 344

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) promote industry best practices and responsible approaches to AI development and use self-regulatory commitments as a criterion for public procurement projects or as a factor that allows more opportunities to use and share data responsibly;

Or. en

Amendment 345
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) offer tax breaks for doing research, better access to computer capacities and datasets, an EU-Visa schema for tech-talents, temporary support in technology scouting or in paying salaries of AI specialists, and state aid exemptions in the area of AI education, training and reskilling of employees;

Or. en

Amendment 346
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 55 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) reduce extensive reporting, information or documentation obligations, establish a single EU online

portal in different languages concerning all necessary procedures and formalities to operate in another EU country, a single point of contact in the home country that can certify the company's eligibility to provide services in another EU country as well as a standardized EU-wide VAT declaration in the respective native language.

Or. en

Amendment 347

Axel Voss, Deirdre Clune, Eva Maydell

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 *SME's and start-ups* shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size, *by granting subsidies or even exempting SMEs and start ups from paying.*

Or. en

Amendment 348

Axel Voss, Deirdre Clune, Eva Maydell

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. The Board shall have a Secretariat, a strong mandate as well as sufficient resources and skilled personnel at its disposal for the assistance in the performance of its tasks laid down in*

Amendment 349

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point a

Text proposed by the Commission

- (a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

Amendment

- (a) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

Amendment 350

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point c

Text proposed by the Commission

- (c) assist the national supervisory authorities and *the Commission* in ensuring the consistent application of this Regulation.

Amendment

- (c) assist the *Commission*, national supervisory authorities and *other competent authorities* in ensuring the consistent application of this Regulation, *in particular in line with the consistency mechanism referred to in Article 59a(3);*

Amendment 351

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

- (c a) *provide particular oversight,*

monitoring and regular dialogue with the providers of general purpose AI systems about their compliance with the Regulation. Any such meeting shall be open to national supervisory authorities, notified bodies and market surveillance authorities to attend and contribute

Or. en

Amendment 352

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 56 – paragraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(c b) bring together national metrology and benchmarking authorities to provide guidance to address the technical aspects of how to measure appropriate levels of accuracy and robustness.

Or. en

Amendment 353

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 1

Text proposed by the Commission

Amendment

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority, ***and the European Data Protection Supervisor***. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

1. The Board shall be composed of the national supervisory authorities, who shall be represented by the head or equivalent high-level official of that authority. Other national authorities may ***also*** be invited to the meetings, where the issues discussed are of relevance for them.

The European Data Protection Supervisor, the Chairperson of the EU Agency for Fundamental Rights, the Executive director of the EU Agency for

Cybersecurity, the Chair of the High Level Expert Group on AI, the Director-General of the Joint Research Centre, and the presidents of the European Committee for Standardization, the European Committee for Electrotechnical Standardization, and the European Telecommunications Standards Institute shall be invited as permanent observers with the right to speak but without voting rights.

Or. en

Amendment 354

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 2

Text proposed by the Commission

2. The Board shall adopt its rules of procedure by a simple majority of its members, *following the consent of the Commission*. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.

Amendment

2. The Board shall adopt its rules of procedure by a simple majority of its members. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish *standing or temporary* sub-groups as appropriate for the purpose of examining specific questions.

Or. en

Amendment 355

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 3

Text proposed by the Commission

3. The Board shall be chaired by the Commission. The *Commission* shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with

Amendment

3. The Board shall be chaired by the Commission. The *Board's Secretariat* shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with

its rules of procedure. The **Commission** shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

its rules of procedure. The **Board's Secretariat** shall *also* provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 356

Axel Voss, Deirdre Clune, Eva Maydell

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, representatives of affected persons, researchers, standardisation organisations, testing and experimentation facilities*, to attend its meetings *in order to ensure accountability and appropriate participation of external actors*. The Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Or. en

Amendment 357

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 57 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. *Without prejudice to paragraph 4, the Board's Secretariat shall organise four additional meetings between the Board and the High Level Expert Group on AI to allow them to share their*

practical and technical expertise every quarter of the year.

Or. en

Amendment 358

Axel Voss, Deirdre Clune, Eva Maydell

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 awareness raising initiatives on Artificial Intelligence and the Regulation*;

Or. en

Amendment 359

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;

Amendment

(b) contribute to uniform administrative practices in the Member States, including for the *assessment, establishing, managing with the meaning of fostering cooperation and guaranteeing consistency among regulatory sandboxes, and* functioning of regulatory sandboxes referred to in Article 53;

Or. en

Amendment 360

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission

Amendment

(iii a) on the need for the amendment of each of the Annexes as referred to in Article 73 as well as all other provisions in this Regulation that the Commission can amend, in light of the available evidence.

Or. en

Amendment 361

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii b (new)

Text proposed by the Commission

Amendment

(iii b) on activities and decisions of Member States regarding post-market monitoring, information sharing, market surveillance referred to in Title VIII;

Or. en

Amendment 362

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii c (new)

Text proposed by the Commission

Amendment

(iii c) on developing common criteria for market operators and competent authorities having the same understanding of concepts such as the 'generally acknowledged state of the art' referred to in Article 9 (3), 'foreseeable risks' referred to in Articles 9 (2) (a), 'foreseeable misuse' referred to in Article 3 (13), Article 9 (2) (b), Article 9 (4), Article 13 (3)(b)(iii) and Article 14 (2), and the 'type and degree of transparency'

referred in Article 13 (1);

Or. en

Amendment 363

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii d (new)

Text proposed by the Commission

Amendment

(iii d) verify alignment with the legal acts listed in Annex II, including with the implementation matters related to those acts.

Or. en

Amendment 364

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) carry out annual reviews and analyses of the complaints sent to and findings made by national supervisory authorities, of the serious incidents reports referred to in Article 62, and of the new registration in the EU Database referred to in Article 60 to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens that are not adequately addressed by this Regulation;

Or. en

Amendment 365

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(c b) carry out biannual horizon scanning and foresight exercises to extrapolate the impact the trends and emerging issues can have on the Union;

Or. en

Amendment 366

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(c c) annually publish recommendations to the Commission, in particular on the categorization of prohibited practices, high-risk systems, and codes of conduct for AI systems that are not classified as high-risk;

Or. en

Amendment 367

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(c d) encourage and facilitate the drawing up of codes of conduct as referred to in Article 69;

Or. en

Amendment 368

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(c e) coordinate among national supervisory authorities and make sure that the consistency mechanism in Article 59a(3) is observed;

Or. en

Amendment 369

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(c f) adopt binding decisions for national supervisory authorities in case the consistency mechanism is not able to solve the conflict among national supervisory authorities as it is clarified in Article 59a(6);

Or. en

Amendment 370

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission

Amendment

(c g) issue yearly reports on the implementation of the Regulation, including an assessment of the impact of the Regulation on economic operators.

Or. en

Amendment 371

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 58 a (new)

Text proposed by the Commission

Amendment

Article 58 a

***Guidelines from the Commission on the
implementation of this Regulation***

***Upon the request of the Member States or
the Board, or on its own initiative, the
Commission shall issue guidelines on the
practical implementation of this
Regulation and in particular on:***

- (i) the application of the requirements
referred to in Articles 8 - 15;***
- (ii) the prohibited practices referred to in
Article 5;***
- (iii) the practical implementation of the
provisions related to substantial
modification;***
- (iv) the identification and application of
criteria and use cases related to high risk
AI systems referred to in Annex III;***
- (v) the practical implementation of
transparency obligations laid down in
Article 52;***
- (vi) the relationship of this Regulation
with other relevant Union legislation.***

***When issuing such guidelines, the
Commission shall pay particular attention
to the needs of SMEs and start-ups as well
as sectors most likely to be affected by this
Regulation.***

Or. en

Amendment 372
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Title VI – Chapter 2 – title

Text proposed by the Commission

Amendment

2 national **competent** authorities

national **supervisory** authorities

Or. en

Amendment 373

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – title

Text proposed by the Commission

Amendment

Designation of national **competent**
authorities

Designation of national **supervisory**
authorities

Or. en

Amendment 374

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 1

Text proposed by the Commission

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. National competent authorities*** shall be organised so as to safeguard the objectivity and impartiality of ***their*** activities and tasks.

1. Each Member State ***shall establish or designate one*** national ***supervisory authority, which*** shall be organised so as to safeguard the objectivity and impartiality of ***its*** activities and tasks.

Or. en

Amendment 375

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 2

Text proposed by the Commission

Amendment

2. ***Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority.***

2. ***The national supervisory authority shall be in charge to ensure the application and implementation of this Regulation. With regard to high-risk AI systems, related to products to which legal acts listed in Annex II apply, the competent authorities designated under those legal acts shall continue to lead the administrative procedures. However, to the extent a case involves aspects covered by this Regulation, the competent authorities shall be bound by measures issued by the national supervisory authority designated under this Regulation.*** The national supervisory authority shall ***also*** act as notifying authority and market surveillance authority.

Or. en

Amendment 376

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 3

Text proposed by the Commission

Amendment

3. Member States shall inform the Commission of their ***designation or designations and, where applicable, the reasons for designating more than one authority.***

3. ***The national supervisory authority in each Member State shall be the lead authority, ensure adequate coordination and act as single point of contact for this Regulation.*** Member States shall inform the Commission of their designations.

Or. en

Amendment 377

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 4

Text proposed by the Commission

4. Member States shall ensure that national ***competent authorities are*** provided with adequate financial and human resources to fulfil ***their*** tasks under this Regulation. In particular, national ***competent*** authorities shall have a sufficient number of ***personnel*** permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks ***and*** knowledge of existing standards and legal requirements.

Amendment

4. Member States shall ensure that national ***supervisory authority is*** provided with adequate financial and human resources to fulfil ***its*** tasks under this Regulation. In particular, national ***supervisory*** authorities shall have a sufficient number of permanently available ***personnel***, whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data, ***data protection*** and data computing, ***cybersecurity, competition law***, fundamental rights, health and safety risks ***as well as*** knowledge of existing standards and legal requirements.

Or. en

Amendment 378

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 379

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 59 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. *Any information and documentation obtained by the national supervisory authorities pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.*

Or. en

Amendment 380

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 59 – paragraph 5**

Text proposed by the Commission

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national ***competent authorities*** with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Amendment

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national ***supervisory authority*** with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Or. en

Amendment 381

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 59 – paragraph 6**

Text proposed by the Commission

6. The Commission shall facilitate the exchange of experience between national ***competent*** authorities.

Amendment

6. The Commission ***and board*** shall facilitate the exchange of experience between national ***supervisory*** authorities.

Or. en

Amendment 382
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 59 – paragraph 7

Text proposed by the Commission

7. National **competent** authorities may provide guidance and advice on the implementation of this Regulation, including to **small-scale providers**. Whenever national **competent** authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent **national** authorities under that Union legislation shall be consulted, as appropriate. **Member States may also establish one central contact point for communication with operators.**

Amendment

7. National **supervisory** authorities may provide guidance and advice on the implementation of this Regulation, including to **SMEs and start-ups, as long as it is not in contradiction with the Board's or the Commission's guidance and advice**. Whenever national **supervisory** authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent authorities under that Union legislation shall be consulted, as appropriate.

Or. en

Amendment 383
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 59 a (new)

Text proposed by the Commission

Amendment

Article 59 a

Consistency mechanism for cross-border cases

- 1. Each national supervisory authority shall perform the tasks assigned to and the exercise of the powers conferred on it in accordance with this Regulation on the territory of its own Member State.**
- 2. The national supervisory authority of the Member State where the provider's place of central administration in the Union is present or established shall be competent to act as lead national supervisory authority for a cross-border**

case that involves an AI-system that falls under this Regulation and that is being placed on the market or put into service in two or more Member States.

3. In order to contribute to the consistent application of this Regulation throughout the Union, national supervisory authorities shall cooperate with each other and, where relevant, with the Commission and the Board, through the consistency mechanism as set out in the following paragraphs.

4. The lead national supervisory authority shall cooperate with the other supervisory authorities in an endeavour to reach consensus. The lead national supervisory authority and the other national supervisory authorities concerned shall exchange all relevant information with each other, provide mutual assistance and execute joint operations.

5. The lead national supervisory authority shall, without delay, communicate the relevant information on the matter to the other national supervisory authorities concerned. It shall without delay submit a draft decision to the other national supervisory authorities concerned for their opinion and take due account of their views.

6. In case the Board, after being notified by another national supervisory authority, finds that the lead national supervisory authority did not use its investigative, corrective or authorisation power despite being notified by another national supervisory authority or came to a decision that is clearly incompatible with provisions of this Regulation, other national supervisory authorities may address the case on their own, taking into account the procedure described in paragraph 3 or request that the Board issue a binding decision.

Or. en

Amendment 384

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 60 – paragraph 1

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems ***referred to in Article 6(2)*** which are registered in accordance with Article 51.

Amendment

1. The Commission shall, in collaboration with the Member States ***and by building on the existing Business Registries in line with Directive 2012/17/EU***, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems ***listed in Annex III*** which are registered in accordance with Article 51.

Or. en

Amendment 385

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 60 – paragraph 2

Text proposed by the Commission

2. The ***data listed in Annex VIII*** shall ***be entered into the EU database by the providers. The Commission shall provide them with technical and administrative support.***

Amendment

2. The ***post-market monitoring system*** shall ***actively and systematically collect, document and analyse relevant data provided by users or collected through other sources, to the extent such data are readily accessible to the provider and taking into account the limits resulting from data protection, copyright and competition law, on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.***

Or. en

Amendment 386
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 60 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The EU database shall not contain any confidential business information or trade secrets of a natural or legal person, including source code.

Or. en

Amendment 387
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 60 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Any information and documentation obtained by the Commission and Member States pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

Amendment 388
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 61 – paragraph 1

Text proposed by the Commission

Amendment

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the ***nature of the artificial intelligence technologies and*** the risks of the high-risk

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the risks of the high-risk AI system.

AI system.

Or. en

Amendment 389

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems ***throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.***

Amendment

2. ***In order to allow the provider to evaluate the compliance of AI systems with the requirements set out in Title III, Chapter 2 throughout their lifetime,*** the post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources, ***to the extent such data are readily accessible to the provider and taking into account the limits resulting from data protection, copyright and competition law,*** on the performance of high-risk AI systems.

Or. en

Amendment 390

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Title VIII – Chapter 2 – title

Text proposed by the Commission

2 Sharing of information on incidents ***and malfunctioning***

Amendment

Sharing of information on incidents

Or. en

Amendment 391

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – title

Text proposed by the Commission

Reporting of serious incidents *and of malfunctioning*

Amendment

Reporting of serious incidents

Or. en

Amendment 392

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems placed on the Union market shall report any serious incident *or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights* to the market surveillance authorities of the Member States where that incident *or breach* occurred.

Amendment

1. Providers of high-risk AI systems placed on the Union market shall report any serious incident to the market surveillance authorities of the Member States where that incident occurred.

Or. en

Amendment 393

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Such notification shall be made *immediately* after the provider has established a causal link between the AI system and the incident *or malfunctioning* or the reasonable likelihood of such a link, and, in any event, not later than **15 days** after the providers becomes aware of the

Amendment

Such notification shall be made *without undue delay* after the provider has established a causal link between the AI system and the *serious* incident or the reasonable likelihood of such a link, and, in any event, not later than **72 hours** after the providers becomes aware of the serious

serious incident *or of the malfunctioning*.

incident.

Or. en

Amendment 394

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

No report under this Article is required if the serious incident also leads to reporting requirements under other laws. In that case, the authorities competent under those laws shall forward the received report to the national competent authority.

Or. en

Amendment 395

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 62 – paragraph 2

Text proposed by the Commission

Amendment

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.

2. Upon receiving a notification related to a ***serious incident referred to in Article 3(44)***, the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.

Or. en

Amendment 396
Axel Voss, Deirdre Clune, Eva Maydell

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 point 5(b) of Annex III which are placed on the market or put into service by providers that are ***subject to regulations that require solutions equivalent to those set out in this Regulation,*** the notification of serious incidents shall be limited to those ***referred to in Article 3(44).***

Or. en

Amendment 397
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 63 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. For the purpose of regulating high-risk AI systems, Market surveillance authorities may have the power to:

(a) carry out unannounced on-site and remote inspections of high-risk AI systems;

(b) acquire samples related to high-risk AI systems, including through remote inspections, to reverse-engineer the AI systems and to acquire evidence to identify non-compliance.

Or. en

Amendment 398
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission

1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted ***full*** access to ***the*** training, validation and testing datasets used by the provider, ***including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.***

Amendment

1. ***When appropriate and proportionate, market surveillance authorities may request*** access to data and documentation in the context of their activities. The market surveillance authorities shall ***only*** be granted, access to ***those*** training, ***machine-learning*** validation and testing datasets used by the provider ***that are relevant and strictly necessary for the purpose of its request, after it has been clearly demonstrated that the data and documentation provided under paragraph 1 was not sufficient to assess conformity.***

Or. en

Amendment 399
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 64 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Providers may challenge requests through an appeal procedure made available by Member States.

Or. en

Amendment 400
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 64 – paragraph 2

Text proposed by the Commission

Amendment

2. ***Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.***

deleted

Or. en

Amendment 401

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 64 – paragraph 4

Text proposed by the Commission

Amendment

4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the list to the Commission and all other Member States and keep the list up to date.

4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. Member States shall notify the list to the Commission and all other Member States and keep the list up to date. ***The European Commission shall publish in a dedicated website the list of all the Competent authorities designated by the Member States in accordance with this article.***

Or. en

Amendment 402

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 67

Text proposed by the Commission

Amendment

Article 67

deleted

Compliant AI systems which present a risk

- 1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.***
- 2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.***
- 3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.***
- 4. The Commission shall without delay enter into consultation with the Member States and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide***

whether the measure is justified or not and, where necessary, propose appropriate measures.

5. The Commission shall address its decision to the Member States.

Or. en

Amendment 403

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 68 – paragraph 1 – point b

Text proposed by the Commission

(b) the *conformity* marking has not been affixed;

Amendment

(b) the *CE* marking has not been affixed;

Or. en

Amendment 404

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 68 – paragraph 2

Text proposed by the Commission

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take *all appropriate* measures to restrict or prohibit the high-risk AI system being made available on the market *or ensure that it is recalled or withdrawn from the market.*

Amendment

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take *proportionate* measures to restrict or prohibit the high-risk AI system being made available on the market.

Or. en

Amendment 405

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

***Right to lodge a complaint with a
supervisory authority***

1. Every citizen who considers that his or her right to protection of personal data has been infringed by the use of a prohibited AI system or a high-risk AI system shall have the right to lodge a complaint with the authority in charge to handle complaints under Article 77 of Regulation (EU) 2016/679 in the Member State of his or her habitual residence, place of work or place of the alleged infringement.

2. The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint.

Or. en

Amendment 406

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 69 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. The Commission and the Board shall encourage and facilitate the drawing up of Codes of Conduct intended to foster the voluntary application of the concept of trustworthy AI set out in Article 4(a) to AI systems other than high-risk AI systems on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the system.

Or. en

Amendment 407
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission

4. The Commission and the Board shall take into account the specific interests and needs of the *small-scale providers* and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Amendment

4. The Commission and the Board shall take into account the specific interests and needs of the *SMEs* and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. en

Amendment 408
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

1. National competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Amendment

1. National competent *authorities, market surveillance* authorities and notified bodies involved in the application of this Regulation shall *put effective cybersecurity, technical and organisational measures in place to ensure* respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

Amendment 409
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 70 – paragraph 1 – point a

Text proposed by the Commission

(a) intellectual property rights, and confidential business information or trade

Amendment

(a) intellectual property rights, and confidential business information or trade

secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

secrets of a natural or legal person *in line with the 2016 EU Trade Secrets Directive (Directive 2016/943) as well as the 2004 Directive on the enforcement of intellectual property rights (Directive 2004/48/EC)*, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.

Or. en

Amendment 410

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 70 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the principles of purpose limitation and data minimization, meaning that national competent authorities minimize the quantity of data requested for disclosure in line with what is absolutely necessary for the perceived risk and its assessment, and they must not keep the data for any longer than absolutely necessary.

Or. en

Amendment 411

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 70 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. In cases where the activity of national competent authorities, market surveillance authorities and notified bodies pursuant to the provisions of this

Article results in a breach of intellectual property rights, Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights in full application of Directive 2004/48/EC on the enforcement of intellectual property rights.

Or. en

Amendment 412

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 70 – paragraph 4**

Text proposed by the Commission

4. The Commission and Member States may exchange, where necessary, 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, ***if consistent with the provisions contained in EU trade agreements with third countries,*** exchange, where necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Or. en

Amendment 413

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 71 – paragraph 1**

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly

and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of *small-scale providers* and start-up and their economic viability.

and effectively implemented *and aligned with the guidelines issued by the European Artificial Intelligence Board, as referred in Article 58 (c) (iii)*. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of *SMEs* and start-up and their economic viability.

Or. en

Amendment 414

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 2

Text proposed by the Commission

2. *The* Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Amendment

2. Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Or. en

Amendment 415

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. *The following infringements* shall be subject to administrative fines of up to **30 000 000** EUR or, if the offender is company, up to **6** % of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Amendment

3. *Non-compliance with the prohibition of the AI practices referred to in Article 5* shall be subject to administrative fines of up to **20 000 000** EUR or, if the offender is company, up to **4%** of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 416
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 3 – point a

Text proposed by the Commission

Amendment

(a) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

deleted

Or. en

Amendment 417
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) non-compliance of the AI system with the requirements laid down in Article 10.

deleted

Or. en

Amendment 418
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 4

Text proposed by the Commission

Amendment

4. The non-compliance of the AI system with *any* requirements or obligations under this Regulation, other than those laid down in Articles 5 *and* 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

4. The *grossly negligent* non-compliance of the *provider or user of the* AI system with *the respective* requirements or obligations under this Regulation, other than those laid down in Articles 5, shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher, *and in case of SMEs and start-ups, up to 1% of its*

worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 419

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 5

Text proposed by the Commission

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher ***and in case of SMEs and start-ups, up to 1% of its worldwide annual turnover for the preceding financial year, whichever is higher.***

Or. en

Amendment 420

Axel Voss, Deirdre Clune, Eva Maydell

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 whether to impose a fine or*** on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Amendment 421

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point a

Text proposed by the Commission

- (a) the nature, gravity and duration of the infringement and of its consequences;

Amendment

- (a) the nature, gravity and duration of the infringement and of its consequences ***taking into account the nature, scope or purpose of the AI system concerned, as well as the number of individuals affected, and the level of damage suffered by them;***

Or. en

Amendment 422

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c

Text proposed by the Commission

- (c) the size and market share of the operator committing the infringement;

Amendment

- (c) the size, ***the annual turnover*** and market share of the operator committing the infringement;

Or. en

Amendment 423

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c a (new)

Text proposed by the Commission

Amendment

- (c a) any action taken by the provider to mitigate the harm or damage suffered by the affected persons;***

Or. en

Amendment 424

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the intentional or negligent character of the infringement;

Or. en

Amendment 425

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c c (new)

Text proposed by the Commission

Amendment

(c c) the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Or. en

Amendment 426

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 71 – paragraph 6 – point c c (new)

Text proposed by the Commission

Amendment

(c c) any relevant previous infringements by the provider;

Or. en

Amendment 427

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 6 – point c e (new)

Text proposed by the Commission

Amendment

(c e) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement;

Or. en

Amendment 428
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 6 – point c e (new)

Text proposed by the Commission

Amendment

(c e) the manner in which the infringement became known to the national competent authority, in particular whether, and if so to what extent, the provider notified the infringement;

Or. en

Amendment 429
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 6 – point c g (new)

Text proposed by the Commission

Amendment

(c g) in the context of paragraph 5 of this Article, the intentional or unintentional nature of the infringement.

Or. en

Amendment 430
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. Administrative fines shall not be applied to a participant in a regulatory sandbox, who was acting in line with the recommendation issued by the supervisory authority.

Or. en

Amendment 431
Axel Voss, Deirdre Clune

Proposal for a regulation
Article 71 – paragraph 8 b (new)

Text proposed by the Commission

Amendment

8 b. The penalties referred to in this article as well as the associated litigation costs and indemnification claims may not be the subject of contractual clauses or other form of burden-sharing agreements between the providers and distributors, importers, users, or any other third-parties.

Or. en

Amendment 432
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 71 – paragraph 8 c (new)

Text proposed by the Commission

Amendment

8 c. The exercise by the market surveillance authority of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with

Union and Member State law, including effective judicial remedy and due process.

Or. en

Amendment 433

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 73 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall undergo due process, be proportionate and be based on a permanent and institutionalised exchange with the relevant stakeholders as well as the Board and the High Level Expert Group on AI.

Or. en

Amendment 434

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 80 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

In Article 5 of Regulation (EU) 2018/858 the following *paragraph* is added:

In Article 5 of Regulation (EU) 2018/858 the following *paragraphs* are added:

Or. en

Amendment 435

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 80 – paragraph 1

Regulation (EU) 2018/858

Article 5

Text proposed by the Commission

Amendment

4 a. *The Commission shall, prior to fulfilling the obligation pursuant to paragraph 4, provide a reasonable explanation based on a gap analysis of existing sectoral legislation in the automative sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principle.*

Or. en

Amendment 436

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 82 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

In Article 11 of Regulation (EU) 2019/2144, the following *paragraph is* added:

In Article 11 of Regulation (EU) 2019/2144, the following *paragraphs are* added:

Or. en

Amendment 437

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 82 – paragraph 1

Regulation (EU) 2019/2144

Article 11

Text proposed by the Commission

Amendment

3 a. *The Commission shall, prior to fulfilling the obligation pursuant to paragraph 3, provide a reasonable explanation based on a gap analysis of existing sectoral legislation in the automative sector to determine the*

existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principle.

Or. en

Amendment 438

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 83 – paragraph 2

Text proposed by the Commission

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their design or intended purpose.

Amendment

2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes *as defined in Article 3(23)* in their design or intended purpose, *and those changes are not needed to comply with applicable existing or new legislation, or to provide security fixes.*

Or. en

Amendment 439

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 84 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. Any amendment to this Regulation pursuant to paragraph 7, or relevant future delegated or implementing acts, which concern sectoral legislation listed in annex II section B, shall take into account the regulatory specificities of each sector, and should not interfere with

*existing governance, conformity
assessment and enforcement mechanisms
and authorities established therein.*

Or. en

Amendment 440

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 85 – paragraph 2

Text proposed by the Commission

2. This Regulation shall apply from
[**24** months following the entering into
force of the Regulation].

Amendment

2. This Regulation shall apply from
[**48** months following the entering into
force of the Regulation].

Or. en

Amendment 441

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 85 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

*(b a) Title II shall apply from [24
months following the entry into force of
this Regulation].*

Or. en

Amendment 442

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 85 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

*3 a. Member States shall not until ...
[24 months after the date of application of
this Regulation] impede the making
available of AI systems and products*

which were placed on the market in conformity with Union harmonisation legislation before [the date of application of this Regulation].

Or. en

Amendment 443

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 85 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. At the latest by six months after entry into force of this Regulation, the European Commission shall submit a standardization request to the European Standardisation Organisations in order to ensure the timely provision of all relevant harmonised standards that cover the essential requirements of this regulation. Any delay in submitting the standardisation request shall add to the transitional period of 24 months as stipulated in paragraph 4

Or. en

Amendment 444

Axel Voss, Deirdre Clune

Proposal for a regulation

Annex I – point b

Text proposed by the Commission

Amendment

(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;

deleted

Or. en

Amendment 445
Axel Voss, Deirdre Clune

Proposal for a regulation
Annex I – point c

Text proposed by the Commission

Amendment

(c) Statistical approaches, Bayesian estimation, search and optimization methods.

deleted

Or. en

Amendment 446
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex II – Part A – point 6

Text proposed by the Commission

Amendment

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

deleted

Or. en

Amendment 447
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex II – Part A – point 11

Text proposed by the Commission

Amendment

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC

deleted

and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;

Or. en

Amendment 448

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex II – Part A – point 12

Text proposed by the Commission

Amendment

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

deleted

Or. en

Amendment 449

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex II – Part B – point 7 a (new)

Text proposed by the Commission

Amendment

7 a. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;

Or. en

Amendment 450

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex II – Part B – point 7 b (new)

Text proposed by the Commission

Amendment

7 b. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Amendment 451

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Annex III – title**

Text proposed by the Commission

Amendment

**HIGH-RISK AI SYSTEMS REFERRED
TO IN ARTICLE 6(2)**

**CRITICAL USE CASES REFERRED TO
IN ARTICLE 6(2)**

Or. en

Amendment 452

Axel Voss, Deirdre Clune, Eva Maydell

**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 mentioned under points 1-8 stand for critical use cases and are each considered to be high-risk AI systems pursuant to Article 6(2), when - according to their instructions to use - their intended purpose and specific use pose a significant risk of harm to the health and safety or a risk of adverse impact on fundamental rights:

Or. en

Amendment 453
Axel Voss, Deirdre Clune

Proposal for a regulation
Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

Amendment

1. Biometric identification **and**
categorisation of natural persons:

1. Biometric identification **systems, excluding biometric authentication or verification, intended to be used for the ‘real-time’ and ‘post’ remote biometric identification or** categorisation of natural persons (**i.e., revealing their identity or tracking their behaviour**) without their expressed or implied consent and causing legal effects or discrimination against the affected person;

Or. en

Amendment 454
Axel Voss, Deirdre Clune

Proposal for a regulation
Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) **AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;**

deleted

Or. en

Amendment 455
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex III – paragraph 1 – point 2 – point a

Text proposed by the Commission

Amendment

(a) AI systems **intended to be** used as safety components in the management and operation of road traffic **and the supply of**

(a) AI systems used as safety **or security** components in the management and operation of road traffic **to the extent**

water, gas, heating and electricity.

that they are not embedded in a vehicle;

Or. en

Amendment 456

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) AI systems intended to be used as safety or security components in the management and operation of the supply of water, gas, heating and electricity, provided the failure of the AI system is highly likely to lead to an imminent threat to such supply.

Or. en

Amendment 457

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 3 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used for the purpose of determining *access or assigning* natural persons to educational and vocational training institutions;

(a) AI systems intended to be used for the purpose of determining *or materially influence decision on the admission of* natural persons to educational and vocational training institutions;

Or. en

Amendment 458

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 3 – point b

Text proposed by the Commission

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to ***educational*** institutions.

Amendment

(b) AI systems intended to be used for the purpose of assessing ***the learning outcome of*** students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to ***these*** institutions.

Or. en

Amendment 459

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 4 – introductory part

Text proposed by the Commission

4. Employment, ***workers management and access to self-employment:***

Amendment

4. Employment ***and work-related contractual relationships***

AI systems intended to be used to make or materially influence decisions on:

(i) recruitment or selection of natural persons, specifically for screening or filtering applications, evaluating candidates in the course of interviews or tests;

(ii) promotion and termination of work-related contractual relationships;

(iii) task allocation based on individual behaviour or personal traits or characteristics; or

(iv) monitoring and evaluating the performance and behaviour of persons.

where those decisions are likely to pose a significant risk of adversely impacting fundamental rights or threatening harm to health and safety.

Or. en

Amendment 460

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;

deleted

Or. en

Amendment 461

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

Amendment

(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.

deleted

Or. en

Amendment 462

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant,

(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate ***and decide on*** the eligibility of natural persons for public assistance benefits and services, as well as

reduce, revoke, or reclaim such benefits and services;

to grant, reduce, revoke, or reclaim such benefits and services;

Or. en

Amendment 463

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission

Amendment

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

deleted

Or. en

Amendment 464

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk *of* a natural person for offending or reoffending or the risk for potential *victims* of criminal offences;

(a) AI systems intended to be used by law enforcement authorities *or on their behalf* for making individual risk assessments of natural persons in order to assess the risk *for* a natural person for offending or reoffending or the risk for *a natural person to become a* potential *victim* of criminal offences;

Or. en

Amendment 465

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission

Amendment

(e) AI systems intended to be used by 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;

(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, ***with the exception of AI systems used for compliance with applicable counterterrorism and anti-money laundering legislation;***

Or. en

Amendment 466

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point g

Text proposed by the Commission

Amendment

(g) ***AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.***

deleted

Or. en

Amendment 467

Axel Voss, Deirdre Clune

Proposal for a regulation

Annex III – paragraph 1 – point 8 – introductory part

Text proposed by the Commission

Amendment

8. Administration of justice ***and democratic processes:***

8. Administration of justice:

Or. en

Amendment 468

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a

Text proposed by the Commission

Amendment

(a) AI systems intended to ***assist*** a judicial authority in researching and interpreting facts and the law and ***in*** applying the law to a concrete set of facts.

(a) AI systems intended to ***be used by*** a judicial authority, ***administrative body or on their behalf for*** in researching and interpreting facts and the law and ***for*** applying the law to a concrete set of facts.

Or. en

Amendment 469

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point a

Text proposed by the Commission

Amendment

(a) its intended purpose, the ***person/s developing the system the date*** and the version of the system;

(a) its intended purpose, the ***name of the provider*** and the version of the system;

Or. en

Amendment 470

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point b

Text proposed by the Commission

Amendment

(b) how the AI system ***interacts or can***

(b) how the AI system ***is intended to be***

be used *to interact* with hardware or software that is not part of the AI system itself, where applicable;

used with hardware or software that is not part of the AI system itself, where applicable;

Or. en

Amendment 471

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point c

Text proposed by the Commission

(c) the versions of relevant software or firmware and *any requirement related to* version update;

Amendment

(c) the versions of relevant software or firmware and version update *information for the user, where applicable*;

Or. en

Amendment 472

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point d

Text proposed by the Commission

(d) the description *of all forms in which* the AI system *is placed* on the market or put into service;

Amendment

(d) the description *or list of the various configurations and variants of* the AI system *which are intended to be made available* on the market or put into service;

Or. en

Amendment 473

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 1 – point f

Text proposed by the Commission

(f) *where the AI system is a component of products*, photographs or illustrations *showing external features*,

Amendment

(f) *descriptions and, if applicable*, photographs or illustrations *of the user interface*;

marking and internal layout of those products;

Or. en

Amendment 474

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – introductory part

Text proposed by the Commission

2. A detailed description *of the elements* of the AI system and of the process for its development, including:

Amendment

2. ***Provided that no confidential information or trade secrets are disclosed,*** a detailed description of the AI system and of the process for its development, including:

Or. en

Amendment 475

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point b

Text proposed by the Commission

(b) the design specifications of the system, ***namely the general*** logic of the AI system ***and of the algorithms***; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Amendment

(b) the ***architecture and*** design specifications: ***a description*** of the AI system ***architecture, with a decomposition of its components and interfaces, how they relate to one another and how they provide for the overall processing or*** logic of the AI system; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III,

Amendment 476

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point c

Text proposed by the Commission

Amendment

(c) *the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;* *deleted*

Or. en

Amendment 477

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point d

Text proposed by the Commission

Amendment

(d) *where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);* *deleted*

Or. en

Amendment 478

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex IV – paragraph 1 – point 2 – point g

Text proposed by the Commission

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; **metrics** used to measure accuracy, robustness, **cybersecurity** and compliance with other relevant requirements set out in Title III, 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 **machine-learning** validation and testing data used and their main characteristics; **information** 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);

Or. en

Amendment 479
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex IV – paragraph 1 – point 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) cybersecurity measures put in place.

Or. en

Amendment 480
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex IV – paragraph 1 – point 5

Text proposed by the Commission

Amendment

5. A description of any change made to the system through its lifecycle;

deleted

Or. en

Amendment 481

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex VII – point 4 – point 4.3

Text proposed by the Commission

4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the ***training and*** testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.

Amendment

4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.

Or. en

Amendment 482

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Annex VII – point 4 – point 4.4

Text proposed by the Commission

4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2. ***Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.***

Amendment

4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2.

Or. en

Amendment 483

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex VIII – point 11

Text proposed by the Commission

Amendment

11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.

deleted

Or. en

Amendment 484
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Annex IX – title

Text proposed by the Commission

Amendment

Union legislation ON large-scale IT systems in the area of Freedom, Security and Justice

ANNEX IXa: MODALITIES FOR AN EU AI REGULATORY SANDBOXING WORK PROGRAMME

1. The AI Regulatory Sandboxes shall be part of the EU AI Regulatory Sandboxing Programme ('sandboxing programme') to be established by the Commission in collaboration with Member States.

2. The Commission shall play a complementary role, allowing those Member States with demonstrated experience with sandboxing to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up of these regulatory sandboxes.

3. Participants in the sandboxing programme, in particular small-scale providers, are granted access to pre-deployment services, such as preliminary registration of their AI system, compliance R&D support services, and to all the other relevant elements of the

Union's AI ecosystem and other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities; and to other value-adding services such as standardisation documents and certification, an online social platform for the community, contact databases, existing portal for tenders and grant making and lists of EU investors.

4. The sandboxing programme shall, in a later development phase, look at helping Member States develop and manage two types of regulatory sandboxes: Physical Regulatory Sandboxes for AI systems embedded in physical products or services and Cyber Regulatory Sandboxes for AI systems operated and used on a stand-alone basis, not embedded in physical products or services.

5. The sandboxing programme shall work with the already established Digital Innovation Hubs in Member States to provide a dedicated point of contact for entrepreneurs to raise enquiries with competent authorities and to seek non-binding guidance on the conformity of innovative products, services or business models embedding AI technologies.

6. One of the objectives of the sandboxing programme is to enable firms' compliance with this Regulation at the design stage of the AI system ('compliance-by-design'). To do so, the programme shall facilitate the development of software tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity

7. The sandboxing programme shall be rolled out in a phased fashion, with the various phases launched by the Commission upon success of the previous phase.

8. The sandboxing programme will have a built-in impact assessment procedure to facilitate the review of cost-effectiveness against the agreed-upon objectives. This assessment shall be drafted with input from Member States based on their experiences and shall be included as part of the Annual Report submitted by the Commission to the European Artificial Intelligence Board.

Or. en