European Parliament
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Committee on Transport and Tourism

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AMENDMENTS
74 - 311

Draft opinion
Josianne Cutajar
(PE730.085v01-00)

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

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

AM_Com_LegOpinion

Amendment 74
Alviina Alametsä

Proposal for a regulation
Recital 1

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

Or. en

Amendment 75
Alviina Alametsä

Proposal for a regulation
Recital 5

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

the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council[33] , and it ensures the protection of ethical principles, as specifically requested by the European Parliament[34] .

placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council[33] , and it ensures the protection of ethical principles, as specifically requested by the European Parliament[34] .

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[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 76
Alviina Alametsä

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5 a) Based on research, the training and use of artificial intelligence can furthermore have significant environmental impacts due to both the critical raw material needed to design infrastructures and microprocessors, as well as the energy required by the development, training, tuning and use of an AI system. In order to ensure the dual ecological and digital transition, to which also this act is meant to contribute,

sustainability should therefore be at the core at the European AI framework. Artificial intelligence should not be employed, if it offers a less sustainable alternative than would otherwise be in use. Development and use of AI should be compatible with sustainable environmental resources, including sustainable data sources, power supplies and infrastructures, at all stages of the lifecycle of AI products. Unnecessary data acquisition and processing should be avoided.

Or. en

Amendment 77
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5 a) Welcomes the regulation on artificial intelligence, which aims to create legal certainty and coherence across the EU. Notes however, that the transport and tourism sectors are already regulated by sector specific rules, and recalls the need for ensuring the coherence and complementarity with the existing legislation. To avoid unnecessary overlap and double regulation, this Regulation should only apply when sector specific legislation posing equal or stricter rules is not already in place.

Or. en

Amendment 78
Alviina Alametsä

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 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.	(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of ***inputs and*** 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.

Or. en

Amendment 79
Alviina Alametsä

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) This Regulation should ensure the highest level of protection, in particular when use of biometrics data is involved, in line with the data protection framework of the Union, while fostering research and investment for the development and deployment of AI

systems that can positively contribute to society.

Or. en

Amendment 80
Kateřina Konečná

Proposal for a regulation
Recital 12 a (new)

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

Or. en

Amendment 81
Alviina Alametsä

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12 a) This Regulation should support research and innovation for the application of AI systems in the transport and tourism sectors, while ensuring a high level of protection of public interests, such as health, safety, fundamental rights, the environment and democracy from harmful effects of such systems.

Or. en

Amendment 82
Alviina Alametsä

Proposal for a regulation
Recital 13

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

Or. en

Amendment 83
Kateřina Konečná

Proposal for a regulation
Recital 13

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

Or. en

Amendment 84
Alviina Alametsä

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17 a) AI systems applied to digital labour platforms, platforms for the management of workers, including in the field of transport, can entail a number of risks such as unjust/unnecessary social scoring, rooted in biased data sets or intrusive surveillance practices, which can lead to violation of workers and fundamental rights. This Regulation should therefore aim at protecting the rights of transport workers managed by digital labour platforms and promote transparency, fairness and accountability in algorithmic management, to ensure that workers are aware of how algorithms work, which personal data is issued and how their behaviour affects decisions taken by the automated system.

Or. en

Amendment 85
Alviina Alametsä

Proposal for a regulation
Recital 17 b (new)

Text proposed by the Commission	*Amendment*
	(17 b) In addition, end-users and individuals should have the right to object to a decision taken solely by an AI system, or relying to a significant degree on the output of an AI system, which produces legal effects concerning him or her, or similarly significantly affects him or her.

Or. en

Amendment 86

Jörgen Warborn

Proposal for a regulation
Recital 18

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

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 87

Jörgen Warborn

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA[38] if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or	***deleted***

possible negative consequences.

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

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 88
Jörgen Warborn

Proposal for a regulation
Recital 20

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

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

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 89
Jörgen Warborn

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) ***Each*** use of a 'real-time' remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to ***an express and specific*** authorisation by a judicial authority or by an independent administrative authority of a Member	(21) Use of a 'real-time' remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to authorisation by a judicial authority or by an independent administrative authority of a Member State. The use should be subject

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

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 90
Jörgen Warborn

Proposal for a regulation
Recital 22

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

Or. en

Amendment 91
Jörgen Warborn

Proposal for a regulation
Recital 23

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

for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.

Or. en

Amendment 92
Alviina Alametsä

Proposal for a regulation
Recital 27

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

restriction to international trade, if any.	minimises any potential restriction to international trade, if any.

Or. en

Amendment 93
Kateřina Konečná

Proposal for a regulation
Recital 27

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

Or. en

Amendment 94
Alviina Alametsä

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[39] ,	(29) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[39] ,

Regulation (EU) No 167/2013 of the European Parliament and of the Council[40] , Regulation (EU) No 168/2013 of the European Parliament and of the Council[41] , Directive 2014/90/EU of the European Parliament and of the Council[42] , Directive (EU) 2016/797 of the European Parliament and of the Council[43] , Regulation (EU) 2018/858 of the European Parliament and of the Council[44] , Regulation (EU) 2018/1139 of the European Parliament and of the Council[45] , and Regulation (EU) 2019/2144 of the European Parliament and of the Council[46] , 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.

Regulation (EU) No 167/2013 of the European Parliament and of the Council[40] , Regulation (EU) No 168/2013 of the European Parliament and of the Council[41] , Directive 2014/90/EU of the European Parliament and of the Council[42] , Directive (EU) 2016/797 of the European Parliament and of the Council[43] , Regulation (EU) 2018/858 of the European Parliament and of the Council[44] , Regulation (EU) 2018/1139 of the European Parliament and of the Council[45] , and Regulation (EU) 2019/2144 of the European Parliament and of the Council[46] , it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts. ***In order to avoid substantial legal uncertainty, and to ensure that the provisions of this legal act apply to all sectors concerned by it without undue delays, those acts should be amended to integrate the provisions of this regulation no later than by the application date of this regulation, that is, 24 months after its entry into force.***

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[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

[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

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).	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

Justification

According to expert consultations, the provisions of this regulation will not apply to any of the sectors covered by legislative acts listed in Annex 2b, before being explicitly integrated into them. This means that neither prohibitions, nor safety guidelines for high-risk AI will apply in these sectors, until they are included the legislation in Annex 2b. For this reason, special attention should be given to the need for speedy integration of the provisions, so that the sectors do not go unregulated for an extended period of time and legal uncertainty is avoided.

Amendment 95
Alviina Alametsä

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health ***and*** safety or ***the*** fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The	(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health**,** safety or fundamental rights of persons ***or the environment***, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the

identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.	Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Or. en

Amendment 96
Alviina Alametsä

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.	(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects***, which can have an effect on the health and safety of individuals, for instance in the context of operation and management of critical infrastructure***. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Or. en

Amendment 97
Kosma Złotowski

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies of AI systems intended for the remote biometric	(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.	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 ***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 98
Kosma Złotowski

Proposal for a regulation
Recital 34

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

Or. en

Amendment 99
Alviina Alametsä

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins***, gender***, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and

safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 100
Alviina Alametsä

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety ***and*** fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety***,*** fundamental rights ***and the environment***, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 101
Alviina Alametsä

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) High data quality is essential for the	(44) High data quality is essential for the

performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***shouldbe*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.	performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***should ensure that databases contain adequate data on groups which are more vulnerable to discriminatory effects posed by AI, such as people with disabilities, and be*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.
	Or. en

Amendment 102
Henna Virkkunen

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant***,*** ***representative and free of errors*** and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***shouldbe*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.	(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 and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***should be*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems. ***In practice, a sufficient solution for bias monitoring could be achieved by abiding by state-of-the-art security and privacy-preserving standards with regards to data management.***

Or. en

Amendment 103
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative ***and*** free of errors ***and*** complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers shouldbe able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.	(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***, up-to-date,*** free of errors ***to the best extent possible and as*** complete ***as possible*** in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, ***sectorial,*** behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers shouldbe able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection***, update*** and correction in relation to high-risk AI systems.

Or. en

Justification

No data set can be completely free of errors or complete.

Amendment 104
Alviina Alametsä

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47 a) Based on previous experience, it is particularly important to ensure clear requirements and guidelines for interoperability between AI systems both within and amongst different economic sectors, contributing to foster innovation and providing favourable conditions for smaller market actors.

Or. en

Amendment 105
Alviina Alametsä

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(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.	(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. ***These operational constraints should be allowed to be amended in the future, in case increased understanding and technological developments in the field***

lead to the conclusion that they do not constitute the safest possible option.

Or. en

Amendment 106
Kosma Złotowski

Proposal for a regulation
Recital 48

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

Or. en

Amendment 107
Kosma Złotowski

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient	(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.

against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, ***as well as the notified bodies, competent national authorities and market surveillance authorities accessing the data of providers of high risk AI systems,*** also taking into account as appropriate the underlying ICT infrastructure.

Or. en

Amendment 108
Kosma Złotowski

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in	(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation ***in the language of the Member State concerned*** and establish a robust post-market monitoring system***. All elements, from design to future development, must be transparent for the user***. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account

question.

the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 109
Jörgen Warborn

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen***, to the extent they are not prohibited***.	(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the involvement of a notified body in the conformity assessment should be foreseen.

Or. en

Amendment 110
Jörgen Warborn

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) High-risk AI systems should bear the CE marking to indicate their	(67) High-risk AI systems should bear the CE marking to indicate their

conformity with this Regulation so that they can move freely within the internal market. Member States should not create ***unjustified*** obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.	conformity with this Regulation so that they can move freely within the internal market. Member States should not create obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.

Or. en

Amendment 111
Elsi Katainen, Jan-Christoph Oetjen, Caroline Nagtegaal, Ondřej Kovařík

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. ***It is especially important to ensure that SMEs and start-ups can easily access these sandboxes, are actively involved and participate in the development and testing of innovative AI systems, in order to be able to contribute with their knowhow and experience. Their participation should be supported and facilitated.***

Or. en

Justification

It is important to ensure that sandboxes encourage and facilitate the participation of SMEs and start-ups, so that they can have an equal opportunity to join these innovative spaces, develop AI systems further and contribute their sectoral knowledge. This is especially important for transport and tourism sectors with many small-scale providers and companies.

Amendment 112
Henna Virkkunen

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should ***be encouraged to*** establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should establish artificial intelligence regulatory sandboxes ***and make such regulatory sandboxes widely available throughout the Union, in order*** to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Or. en

Justification

Given the comprehensive and often times ambiguous definitions of the AI Act, regulatory sandboxes should be widely used in order to establish a controlled environment to test innovative technologies. An effective regulatory sandboxing scheme can bring significant advantages in terms of innovation and growth without compromising on consumer protection or privacy.

Amendment 113

Kosma Złotowski

Proposal for a regulation
Recital 73

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

Or. en

Amendment 114
Alviina Alametsä

Proposal for a regulation
Recital 73

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

Or. en

Amendment 115
Elsi Katainen, Jan-Christoph Oetjen, Caroline Nagtegaal, Ondřej Kovařík

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the	(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the

requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.	requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence. ***In order to ensure a common and consistent approach to the development of AI and ensure good cooperation and exchange of views, the Board should regularly consult other EU institutions as well as all sector-specific relevant stakeholders.***

Or. en

Amendment 116
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission	*Amendment*
	(77 a) To encourage knowledge sharing from best practices, the Commission should organise regular consultative meetings for knowhow exchange between different Member States' national authorities responsible for notification policy.

Or. en

Amendment 117
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
(c) specific requirements for ***high-risk*** AI systems and obligations for operators of such systems;	(c) specific requirements for AI systems and obligations for operators of such systems;

Or. en

Amendment 118
Jörgen Warborn

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 ***AI systems classified as*** high-risk AI ***in accordance with Article 6 related to*** products ***covered by Union harmonisation legislation listed in Annex II, section B***, only Article 84 of this Regulation shall apply:

Or. en

Justification

Type-approval only covers the vehicle itself, but AI is actually used by the safety components of the vehicle. With the revised paragraph suggested by the Rapporteur, automotive industry experts warn that systems like intelligent speed assistance or automatic emergency braking would fall both under the scope of the AI Act and under the existing sector-specific technical requirements, which would lead to a duplication of requirements, with potential conflicts or discrepancies.

Amendment 119
Kosma Złotowski

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.	3. This Regulation shall not apply to AI systems ***specially designed, modified,*** developed or used exclusively for military purposes.

Or. en

Amendment 120
Jörgen Warborn

Proposal for a regulation
Article 2 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. This Regulation shall not apply to AI systems, including their output, specifically designed and deployed for research and development purposes.

Or. en

Amendment 121
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	5 a. This Regulation shall not apply to AI systems, including their output, that are specifically developed and put into service for the sole purpose of scientific research and development.

Or. en

Amendment 122
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
	5 a. This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research and development.

Or. en

Amendment 123
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
	5 a. This Regulation shall not provide a legal basis for AI development, deployment or use that is unlawful under Union or national law.

Or. en

Amendment 124
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
	5 b. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating the protection of personal data, in particular Regulation (EU) 2016/679, Directive (EU) 2016/680, Regulation (EU)2018/1725, and Directive 2002/57/EC.

Or. en

Amendment 125
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	5 b. This Regulation shall not affect any research and development activity regarding AI systems, in so far as such activity does not lead to or entail placing an AI system on the market or putting it into service.

Or. en

Amendment 126
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
	5 b. This Regulation shall not affect any research and development activity regarding AI systems in so far as such activity does not lead to or entail placing an AI system on the market or putting it into service.

Or. en

Amendment 127
Kosma Złotowski

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 software that ***display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals, which:***
	(a) receives machine and/or human-based data and inputs;
	(b) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with the techniques and approaches listed in Annex I***, and***
	(c) generates outputs ***in the form of*** content ***(generative AI systems)***, predictions, recommendations or decisions***, which influence*** the environments ***it***

interacts with;

Or. en

Amendment 128
Henna Virkkunen

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 system that:***
	(i) receives machine and/or human-based data and inputs,
	(ii) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with the techniques and approaches listed in Annex I***, and***
	(iii) generates outputs ***in the form of*** content ***(generative AI systems)***, predictions, recommendations or decisions***, which influence*** the environments ***it interacts*** with;

Or. en

Justification

New wording is needed to adjust the definition of the AI systems to be applicable to only true AI systems that at some level of autonomy infer how to achieve set objectives and generate relevant output. This clarification would leave out of scope normal programming.

Amendment 129
Alviina Alametsä

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 software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of ***inputs and*** objectives, generate outputs such as content, predictions, recommendations, or decisions;

Or. en

Amendment 130
Henna Virkkunen

Proposal for a regulation
Article 3 – paragraph 1 – point 2

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

Or. en

Justification

New wording is needed to adjust the definition of the AI systems to be applicable to only true AI systems that at some level of autonomy infer how to achieve set objectives and generate relevant output. This clarification would leave out of scope normal programming. The essential justification of this Act is the challenge posed by autonomous, mostly machine learning solutions. These challenges do not materialise when using logic-based systems where all rules are set ex ante by persons developing the system.

Amendment 131
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
	(3 a) 'AI subject' means: any natural or legal person that is subject to a decision based on or assisted by an AI system, or subject to interaction with an AI system or treatment of data relating to them by an AI system, or otherwise subjected to analysis affected by an AI system;

Or. en

Amendment 132
Alviina Alametsä

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(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;	(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 133
Kosma Złotowski

Proposal for a regulation
Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) 'End-user' means any natural person who, in the framework of employment, contract or agreement with the deployer, uses the AI system under the authority of the deployer;

Or. en

Amendment 134
Alviina Alametsä

Proposal for a regulation
Article 3 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) 'end-user' means any natural person who uses the AI system under the authority of the deployer;

Or. en

Amendment 135
Kosma Złotowski

Proposal for a regulation
Article 3 – paragraph 1 – point 11

Text proposed by the Commission	*Amendment*
(11) 'putting into service' means the supply of an AI system for first use directly to the user or ***for own use on the Union market*** for its intended purpose;	(11) 'putting into service' means the supply of an AI system for first use directly to the user or ***the end-user*** for its intended purpose;

Or. en

Amendment 136
Henna Virkkunen

Proposal for a regulation
Article 3 – paragraph 1 – point 12

Text proposed by the Commission	*Amendment*
(12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales	(12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales

materials and statements, as well as in the technical documentation;	materials and statements, as well as in the technical documentation***. General purpose AI systems shall not be considered as having an intended purpose within the meaning of this Regulation***;

Or. en

Amendment 137
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 1 – point 12

Text proposed by the Commission	*Amendment*
(12) '***intended purpose***' means the use for which ***an*** AI system is intended ***by the provider, including the specific context and*** conditions ***of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation***;	(12) '***foreseeable use***' means ***the use that can reasonably be expected to be made of an AI system, including but not limited to*** the use for which ***the*** AI system is intended ***for consumers or the likely use by consumers under reasonably foreseeable*** conditions;

Or. en

Amendment 138
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(13) 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its ***intended*** purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;	(13) 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its purpose ***as indicated in instruction for use or technical specification***, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

Or. en

Amendment 139
Kosma Złotowski

Proposal for a regulation
Article 3 – paragraph 1 – point 14

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

Or. en

Amendment 140
Alviina Alametsä

Proposal for a regulation
Article 3 – paragraph 1 – point 35

Text proposed by the Commission	*Amendment*
(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;	(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, ***disability,*** hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;

Or. en

Amendment 141
Kosma Złotowski

Proposal for a regulation
Article 3 – paragraph 1 – point 36

Text proposed by the Commission	*Amendment*
(36) ‘remote biometric identification system’ means an AI system for the	(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 ***;***	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 that identity is otherwise established – without the conscious cooperation of these persons or against their will – by matching live templates with templates stored in a template database***

Or. en

Amendment 142
Henna Virkkunen

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 ***or malfunctioning of an AI system*** that directly or indirectly leads to any of the following:

Or. en

Amendment 143
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	(b a) breach of obligations under Union law intended to protect fundamental rights;

Or. en

Amendment 144
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	(b b) serious damage to property or the environment;

Or. en

Amendment 145
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	(44 a) 'critical infrastructure' means an asset, system or part thereof which is necessary for the delivery of a service that is essential for the maintenance of vital societal functions or economic activities within the meaning of Article 2(4) and (5) of Directive ____ on the resilience of critical entities

Or. en

Amendment 146
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
	(44 a) 'critical infrastructure' means an asset, system or part thereof which is necessary for the delivery of a service that is essential for the maintenance of vital societal functions or economic activities within the meaning of Article 2(4) and (5) of Directive (…) on the resilience of critical entities;

Or. en

Amendment 147
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	(44 b) 'personal data' means data as defined in point (1) of Article 4 of Regulation (EU) 2016/679;

Or. en

Amendment 148
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	(44 c) '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 149
Jörgen Warborn

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Article 4	***deleted***
Amendments to Annex I	
The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and	

approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Amendment 150
Henna Virkkunen

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and 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.	The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I ***within the scope of the definition of an AI system as provided for in Article 3(1)***, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Amendment 151
Kosma Złotowski

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

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

Or. en

Amendment 152
Kosma Złotowski

Proposal for a regulation
Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) detrimental or unfavourable treatment of certain natural persons or ***whole*** groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected;	(i) ***preferential,*** 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 153
Kosma Złotowski

Proposal for a regulation
Article 5 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) detrimental or unfavourable treatment of certain natural persons or ***whole*** groups thereof that is unjustified or disproportionate to their social behaviour or its gravity;	(ii) ***preferential,*** 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 154
Jörgen Warborn

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

Text proposed by the Commission	*Amendment*
(d) the use of 'real-time' remote biometric identification systems in	***deleted***

publicly accessible spaces for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives:

(i) the targeted search for specific potential victims of crime, including missing children;

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

(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[62] 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.

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

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to

strict control.

Amendment 155
Jörgen Warborn

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

Text proposed by the Commission	*Amendment*
(i) the targeted search for specific potential victims of crime, including missing children;	***deleted***

Or. en

Amendment 156
Alviina Alametsä

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

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

Or. en

Amendment 157
Jörgen Warborn

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

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

Or. en

Amendment 158
Jörgen Warborn

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

Text proposed by the Commission	*Amendment*
(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[62] and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.	***deleted***

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

Or. en

Amendment 159
Jörgen Warborn

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:	***deleted***

(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;

(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 160
Jörgen Warborn

Proposal for a regulation
Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.	***deleted***
The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.	

Or. en

Justification

Many of our cities' transport hubs, train stations etc are highly exposed to crime, and frequent locations for violence and serious disturbances. As we have sadly experienced, they are also prime targets for terrorist attacks. This could be tackled by linking secure and efficient AI systems with facial recognition to the public transport agencies' and law enforcement's surveillance cameras. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, providing a very powerful tool to investigate serious crimes committed in our public transport systems. A ban on the law enforcement to use AI and facial recognition is a fundamentally bad proposal, counteracting our ambitions to make public

transport safer and more attractive, undermining the modal shift towards public transport that we strive for. Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control.

Amendment 161
Jörgen Warborn

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.	***deleted***

Or. en

Amendment 162
Henna Virkkunen

Proposal for a regulation
Article 6 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. ***Irrespective of whether*** an AI system ***is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system*** shall be considered ***high-risk where both of the following conditions are fulfilled:***	1. An AI system ***that is itself a product covered by the Union harmonisation legislation listed in Annex II*** shall be considered ***as high risk if it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the***

above mentioned legislation.

Or. en

Amendment 163
Kateřina Konečná

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;	(a) the AI system is intended to be used as a component ***the failure or malfunctioning of which endangers the health, safety or fundamental rights of persons or of property***, covered by the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 164
Kosma Złotowski

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;	(a) the AI system is intended to be used as ***main*** safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

Or. en

Amendment 165
Henna Virkkunen

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. ***An AI system intended to be used as a safety component of a product covered by the legislation*** referred to in paragraph 1 shall be considered ***as high risk if it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to above mentioned legislation. This provision shall apply irrespective of whether the AI system is placed on the market or put into service independently from the product.***

Or. en

Amendment 166
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
	2 a. In addition to the high-risk AI systems referred to in paragraphs 1 and 2, AI systems that have over 20 million EU citizens across the EU or 50% of any given Member States' population as active monthly users, or whose users have cumulatively over 20 million customers or beneficiaries in the EU affected by it shall be considered high-risk, unless these are placed on to the market or put into service by a public authority.

Or. en

Amendment 167
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
	2 a. The classification as high-risk as a consequence of Article 6(1) and 6(2) shall be disregarded for AI systems whose intended purpose demonstrates that the generated output is a recommendation requiring a human intervention to convert this recommendation into a decision and for AI systems, which do not lead to autonomous decisions or actions of the overall system.

Or. en

Amendment 168
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	2 a. AI systems referred to in Annex III shall be considered high-risk.

Or. en

Amendment 169
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
	2 b. In addition to the high-risk AI systems referred to in paragraph 1, paragraph 2 and paragraph 3, AI systems that create foreseeable high-risks when combined shall also be considered high-risk.

Or. en

Amendment 170
Jörgen Warborn

Proposal for a regulation
Article 7

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 171
Kateřina Konečná

Proposal for a regulation
Article 7 – paragraph 1 – introductory part

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

Or. en

Amendment 172
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;	***deleted***

Or. en

Amendment 173
Kateřina Konečná

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

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

Or. en

Amendment 174
Alviina Alametsä

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

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

Or. en

Amendment 175
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
(b) the AI systems pose a risk of harm	(b) the AI systems pose a ***serious*** risk

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.	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 posed by the high-risk AI systems already referred to in Annex III.

Or. en

Justification

Wording of the Article 7 needs to be stronger to de facto limit Commissions' powers to adopt delegated acts that would essentially change the scope of the Act. Task allocation is best done by AI and as such, does not raise fundamental rights issues.

Amendment 176
Kateřina Konečná

Proposal for a regulation
Article 7 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:	2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights ***or on the environment*** that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account***, including but not limited to,*** the following criteria:

Or. en

Amendment 177
Alviina Alametsä

Proposal for a regulation
Article 7 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:	2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights ***or the environment*** that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Or. en

Amendment 178
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
(a) the intended purpose of the AI system;	(a) the intended purpose ***or reasonably foreseeable use*** of the AI system;

Or. en

Amendment 179
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;	(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights ***or on the environment*** or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Or. en

Amendment 180
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;	(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights ***or the environment*** or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Or. en

Amendment 181
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;	(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons ***or on the environment***;

Or. en

Amendment 182
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;	(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons ***or the environment***;

Or. en

Amendment 183
Alviina Alametsä

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

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

Or. en

Amendment 184
Alviina Alametsä

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall comply with the requirements established in this Chapter.	1. High-risk AI systems shall comply with the requirements established in this Chapter***, taking into account sectoral legislation where applicable***.

Or. en

Amendment 185
Kateřina Konečná

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.	2. The intended purpose of the high-risk AI system***, the foreseeable uses and foreseeable misuses of AI systems within determinate uses*** and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Or. en

Amendment 186
Henna Virkkunen

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Or. en

Justification

The article is very detailed and difficult to read. Therefore it is suggested to remove the detailed requirements on the process and concentrate only on the essential requirements on risk-management systems.

Amendment 187
Henna Virkkunen

Proposal for a regulation
Article 9 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The risk management system ***shall consist of a continuous iterative process***	2. The risk management system shall

run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:

comprise the following steps:

Or. en

Amendment 188
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;	(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system ***that might cause harm or damage to the environment or the health, safety or fundamental rights of persons in view of the intended purpose or misuse of the high-risk AI system.***;

Or. en

Amendment 189
Henna Virkkunen

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 other possibly arising risks based on the analysis of data gathered from the post-market monitoring system;

Or. en

Amendment 190
Henna Virkkunen

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The risk management measures ***referred to in paragraph 2, point (d)*** shall give due consideration to the effects and possible interactions resulting from the 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.	3. The risk management measures 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.

Or. en

Amendment 191
Kosma Złotowski

Proposal for a regulation
Article 9 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user**.**	4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse***, subject to terms, conditions as made available by the provider, and contractual and license restrictions***. Those residual risks shall be communicated to the user

Or. en

Amendment 192
Henna Virkkunen

Proposal for a regulation
Article 9 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. The risk management measures ***referred to in paragraph 2, point (d)*** shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.	4. The risk management measures shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 193
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 5

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

Or. en

Amendment 194
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Testing procedures shall be suitable to achieve the ***intended purpose*** of the AI	6. Testing procedures shall be suitable to achieve the ***foreseeable use*** of the AI

system and do not need to go beyond what is necessary to achieve that purpose.	system and do not need to go beyond what is necessary to achieve that purpose.

Or. en

Amendment 195
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 7

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

Or. en

Amendment 196
Jörgen Warborn

Proposal for a regulation
Article 10 – paragraph 1

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

Or. en

Amendment 197

Kosma Złotowski

Proposal for a regulation
Article 10 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,	2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. ***Where relevant to appropriate risk management measures,*** those practices shall concern in particular,

Or. en

Amendment 198
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(e) ***a prior*** assessment of the availability, quantity and suitability of the data sets that are needed;	(e) ***an*** assessment of the availability, quantity and suitability of the data sets that are needed;

Or. en

Amendment 199
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(f) examination in view of possible biases;	(f) examination in view of possible biases***, that are likely to affect health and safety of persons or lead to discrimination prohibited by Union law***;

Or. en

Amendment 200
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(g) the identification of any ***possible*** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.	(g) the identification of any ***other*** data gaps or shortcomings ***that materially increase the risks of harm to the health, natural environment and safety or the fundamental rights of persons***, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 201
Kosma Złotowski

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 sets or a combination thereof.	3. Training, validation and testing data sets shall be relevant***, sufficiently diverse to mitigate bias, and, to the best extent possible***, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 202
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

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 sets or a combination thereof.	3. Training, validation and testing data sets shall be relevant, representative, ***up-to-date,*** free of errors ***to the best extent possible and as*** complete ***as possible***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Justification

No data set can be completely free of errors or complete.

Amendment 203
Henna Virkkunen

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 sets or a combination thereof.	3. 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 shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Justification

Requirements on dataset to be free from errors and complete are not realistic. The text should guide to critically evaluate where are the limits of the data and whether there are gaps or

flaws in data vis-à-vis the intended purpose of the AI system.

Amendment 204
Jörgen Warborn

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 sets or a combination thereof.	3. Training, validation and testing data sets shall be relevant ***and*** representative. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 205
Kosma Złotowski

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, 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.	4. Training, validation and testing data sets shall ***be sufficiently diverse to accurately capture***, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 206
Kateřina Konečná

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***, 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.	4. Training, validation and testing data sets shall take into account, to the extent required by the ***foreseeable use***, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 207
Alviina Alametsä

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10 a
	Environmental Impact
	1. High-risk AI systems shall be designed and developed making use of state-of-the-art methods to increase energy efficiency, and the overall efficiency of the system. They shall be developed and set up with capabilities enabling the measurement and logging of the energy consumption and other environmental impact the use of the systems may have over their entire lifecycle.
	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 to detail the measurement and logging procedures, taking into account state-of-the-art methods, in particular, to enable the comparability of the environmental impact of systems, and taking into account the economies of scale.

Or. en

Amendment 208
Alviina Alametsä

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 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.	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV ***and be kept up to date throughout its entire lifecycle, and where appropriate, beyond***.

Or. en

Amendment 209
Kosma Złotowski

Proposal for a regulation
Article 12 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The logging capabilities shall ensure a level of traceability of the AI system's functioning ***throughout*** its lifecycle that is appropriate to the intended purpose of the system.	2. The logging capabilities shall ensure a level of traceability of the AI system's functioning ***while the AI system is used within*** its lifecycle that is appropriate to the intended purpose of the system.

Or. en

Amendment 210
Kosma Złotowski

Proposal for a regulation
Article 12 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. For records constituting trade secrets as defined in Article 2 of Directive (EU) 2016/943, provider may elect to confidentially provide such trade secrets only to relevant public authorities to the extent necessary for such authorities to perform their obligations hereunder.

Or. en

Amendment 211
Kosma Złotowski

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.	2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or ***made*** otherwise ***available,*** that include concise, complete, correct and clear information that is ***reasonably*** relevant, accessible and comprehensible to users ***to assist them in operating and maintaining the AI system, taking into consideration the system's intended purpose and the expected audience for the instructions***.

Or. en

Amendment 212
Jörgen Warborn

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 213
Kosma Złotowski

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

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

Or. en

Amendment 214
Kosma Złotowski

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

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

Or. en

Amendment 215
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety ***or*** fundamental rights;	(iii) 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***,*** fundamental rights ***or the environment***;

Or. en

Amendment 216
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(e) the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.	(e) the expected lifetime of the high-risk AI system***, the description of the procedure of withdrawing it from use*** and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.

Or. en

Amendment 217
Alviina Alametsä

Proposal for a regulation
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The Commission may adopt delegated acts in accordance with Article

73 to amend paragraph 1 of this article, in case technological developments and understanding in the field lead to a situation in which, in a limited amount of circumstances, human oversight is proven to compromise the safety of a system.

Or. en

Amendment 218
Kosma Złotowski

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter. ***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, such justification residing in an improved accuracy measured in the outcomes and results delivered by high-risk AI systems.***

Or. en

Amendment 219
Alviina Alametsä

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Human oversight shall aim at	2. Human oversight shall aim at

preventing or minimising the risks to health, safety ***or*** fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.	preventing or minimising the risks to health, safety***,*** fundamental rights ***or the environment*** that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Amendment 220
Kosma Złotowski

Proposal for a regulation
Article 14 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:	4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate ***and proportionate*** to the circumstances:

Or. en

Amendment 221
Henna Virkkunen

Proposal for a regulation
Article 14 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:	4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, ***where necessary and*** as appropriate to the circumstances:

Or. en

Justification

It should be noted that disproportionate, too detailed or overly ambitious requirements for human oversight will result in added cost with little or no added value in terms of risk mitigation. Human oversight requirements should therefore be proportionate and realistic. Value should also be placed on the fact, that AI controlled machines with built-in risk prevention measures have in many cases already been proven to provide lower accident rates compared to human oversight, and the development of such risk prevention measures is continuous.

Amendment 222
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
(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;	(a) ***have an appropriate understanding of*** the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Or. en

Amendment 223
Jörgen Warborn

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

Text proposed by the Commission	*Amendment*
(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;	(a) 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;

Or. en

Amendment 224
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(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;	(a) 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;

Or. en

Amendment 225
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system***;***	(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system ***unless the AI system is considered state-of-the-art and such human intervention is deemed to increase risks or otherwise negatively impact the system's performance.***

Or. en

Amendment 226
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
(e) be able to intervene on the	(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.

operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure ***unless the AI system is considered state-of-the-art and such human intervention is deemed to increase risks or otherwise negatively impact the system’s performance***.

Or. en

Amendment 227
Jörgen Warborn

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

Text proposed by the Commission	*Amendment*
(e) be able to intervene on the operation of the high-risk AI system ***or interrupt*** the system through a “stop” button or a similar procedure.	(e) be able to intervene on the operation of the high-risk AI system***, put the system into fail-safe mode, put the system into manual control mode or stop*** the system through a “stop” button or a similar procedure.

Or. en

Amendment 228
Kosma Złotowski

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission	*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.	5. For high-risk AI systems referred to in point 1(a) of Annex III ***and for which human oversight is effectively justified by a proven end value to the protection of health, safety and fundamental rights***, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been ***separately*** verified and confirmed by at

least two natural persons.

Or. en

Amendment 229
Kosma Złotowski

Proposal for a regulation
Article 15 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
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.	3. ***Providers and deployers should take all appropriate and feasible technical and organizational measures to ensure that*** high-risk AI systems ***are*** resilient as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 230
Kosma Złotowski

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
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***.	1. Users shall ***bear sole responsibility in case of any use of the AI system that is not*** in accordance with the instructions of use accompanying the systems.

Or. en

Amendment 231
Kateřina Konečná

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

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

Or. en

Amendment 232
Jörgen Warborn

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring.	1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. ***These procedures shall be developed in cooperation between the notifying authorities of all Member States and shall result in standard procedures implemented equally in all Member States, with a view to removing administrative barriers and ensuring a seamless single market.***

Or. en

Amendment 233
Jörgen Warborn

Proposal for a regulation
Article 30 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question.	8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for providers and that notified bodies perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question. ***Particular attention shall be paid to minimising administrative burdens and compliance costs for micro, small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC.***

Or. en

Amendment 234
Kosma Złotowski

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Notified bodies shall satisfy the ***organisational, quality management, resources and process*** requirements ***that are necessary to fulfil their tasks.***	2. Notified bodies shall satisfy the ***minimum cybersecurity*** requirements ***set out for public administration entities identified as operators of essential services pursuant to Directive (…) on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148;***

Or. en

Amendment 235
Kosma Złotowski

Proposal for a regulation
Article 33 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.	6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out. ***Any information and documentation obtained by notified bodies pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.***

Or. en

Amendment 236
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Article 39 a (new)

Text proposed by the Commission	*Amendment*
	Article 39 a
	Exchange of knowhow and best practices
	The Commission shall facilitate regular consultative meetings for the exchange of knowhow and best practices between the Member States' national authorities responsible for notification policy.

Or. en

Amendment 237
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
	When issuing a standardisation request to European standardisation organisations in accordance with Article 10 of Regulation 1025/2012, the Commission shall specify that standards are coherent, easy to implement and drafted in a way that aims to fulfil, in particular, the following objectives:
	a) ensure that AI systems placed on the market or put into service in the Union protect public interests, such as health, safety, fundamental rights, the environment and democracy from harmful effects of such systems;
	b) enhance inclusive participation in governance that is representative of all relevant European stakeholders, most notably civil society and researchers, by actively facilitating access of such representatives to relevant fora and processes.

Or. en

Amendment 238
Henna Virkkunen

Proposal for a regulation
Article 41 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right ***concerns***, the Commission may, by means	1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are ***significantly*** insufficient or that there is a need to address specific ***and pressing*** safety or fundamental right ***concern that***

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).	***cannot be sufficiently settled by development of harmonised standards***, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

Justification

The proposal includes very wide powers for the Commission to adopt common specifications on top of harmonised standards. This adds to unpredictability of the act.

Amendment 239
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Valter Flego

Proposal for a regulation
Article 41 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.	2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law***, as well as relevant sector-specific stakeholders***.

Or. en

Amendment 240
Henna Virkkunen

Proposal for a regulation
Article 41 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission, when preparing the common specifications referred to in	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.	paragraph 1, shall gather the views of ***the developers and providers of High-risk AI systems and*** relevant bodies or expert groups established under relevant sectorial Union law.

Or. en

Justification

The proposal includes very wide powers for the Commission to adopt common specifications on top of harmonised standards. This adds to unpredictability of the act. Therefore stronger boundaries should be set for the Commission's use of common specifications.

Amendment 241
Kateřina Konečná

Proposal for a regulation
Article 43 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	A new conformity assessment is always required whenever safety related limits of continuing learning high-risk AI systems maybe exceeded or have an impact on the health or safety.

Or. en

Amendment 242
Alviina Alametsä

Proposal for a regulation
Article 43 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the	6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the

effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health ***and*** safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.	effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health**,** safety**, *the environment*** and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.

Or. en

Amendment 243
Kateřina Konečná

Proposal for a regulation
Article 52 – title

Text proposed by the Commission	*Amendment*
Transparency obligations for ***certain*** AI systems	Transparency obligations for AI systems

Or. en

Amendment 244
Kosma Złotowski

Proposal for a regulation
Article 52 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system***, *unless this is obvious from the circumstances and the context of use***. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	1. Providers shall ensure that AI systems intended to 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. 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 245
Henna Virkkunen

Proposal for a regulation
Article 52 – paragraph 1

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

Or. en

Amendment 246
Kosma Złotowski

Proposal for a regulation
Article 52 – paragraph 3 – introductory part

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

Or. en

Amendment 247
Kateřina Konečná

Proposal for a regulation
Article 52 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. Providers of any AI system should document and make available upon request the parameters regarding the environmental impact, including but not limited to resource consumption, resulting from the design, data management and training, the underlying infrastructures of the AI system, and of the methods to reduce such impact.

Or. en

Amendment 248
Kateřina Konečná

Proposal for a regulation
Article 52 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Paragraphs 1, 2 ***and 3*** shall not affect the requirements and obligations set out in Title III of this Regulation.	4. Paragraphs 1, 2***, 3 and 4*** shall not affect the requirements and obligations set out in Title III of this Regulation.

Or. en

Amendment 249
Henna Virkkunen

Proposal for a regulation
Article 52 a (new)

Text proposed by the Commission	*Amendment*
	Article 52 a
	General purpose AI systems

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

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

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

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

Or. en

Justification

This Article reflects the lines of the Council by the addition of a new article, clarifying the roles and scope of the act and the applicability of the requirements and obligations of the Act.

Amendment 250
Henna Virkkunen

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	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of

innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.	innovative AI systems ***and secure processing of personal data*** for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.

Or. en

Justification

As proposed, the article establishing frameworks for regulatory sandboxes is rather weak. The key thing is the ability to process personal data on an easy and safe manner in the AI regulatory sandbox. The proposal only provides extension for public bodies, but this facility should be extended to private companies as well.

Amendment 251
Kosma Złotowski

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

Or. en

Amendment 252
Henna Virkkunen

Proposal for a regulation
Article 53 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The controllers of personal data referred to in Article 4 (7) of the Regulation (EU) 2016/679 may further process personal data in an AI regulatory sandbox to the extent that it is necessary for the purposes of development, testing and validation of AI systems. Right of processing is subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. This processing shall not be considered incompatible with the initial purposes.

Or. en

Amendment 253
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Valter Flego

Proposal for a regulation
Article 53 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The organisers of AI regulatory sandboxes shall ensure an easy access for SMEs and start-ups by facilitating and supporting their participation and mitigating administrative burden, which might arise from joining.

Or. en

Justification

It is important to ensure that sandboxes encourage and facilitate the participation of SMEs and start-ups, so that they can have an equal opportunity to join these innovative spaces. This is especially important for transport and tourism sectors with many small-scale providers and companies.

Amendment 254
Alviina Alametsä

Proposal for a regulation
Article 53 – paragraph 3

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

Or. en

Amendment 255
Kosma Złotowski

Proposal for a regulation
Article 53 – paragraph 5

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

Or. en

Amendment 256
Henna Virkkunen

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

Or. en

Amendment 257
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
(iii) a high level of protection and improvement of the quality of the environment;	(iii) a high level of protection and improvement of the quality of the environment***, with the prerequisite that the costs of developing the AI system shall not exceed the benefit of developing it for the purpose of protecting the environment***;

Or. en

Amendment 258
Alviina Alametsä

Proposal for a regulation
Article 55 – title

Text proposed by the Commission	*Amendment*
55 Measures for small-scale providers and users	55 Measures for small-scale providers and users ***and start-ups***

Or. en

Amendment 259
Alviina Alametsä

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

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

Or. en

Amendment 260
Alviina Alametsä

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

Text proposed by the Commission	*Amendment*
(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of the small-scale providers and users;	(b) organise specific awareness raising activities about the application of this Regulation tailored to the needs of the small-scale providers and users ***and start-ups***;

Or. en

Amendment 261
Alviina Alametsä

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

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

Or. en

Amendment 262
Kosma Złotowski

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, the European Data Protection Supervisor***, AI ethics experts and industry representatives***. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 263
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

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	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.	high-level official of that authority, and the European Data Protection Supervisor. Other national***, regional and local*** authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 264
Kosma Złotowski

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Board shall be ***chaired*** by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.	3. The Board shall be ***co-chaired*** by the Commission ***and representative chosen from among the delegates of the Member States***. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 265
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Article 57 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. The Board shall organise consultations with stakeholders at least twice a year. Such stakeholders shall include representatives from industry, SMEs and start-ups, civil society organisations such as NGOs, consumer associations, the social partners and

academia, to assess the evolution of trends in technology, issues related to the implementation and the effectiveness of this Regulation, regulatory gaps or loopholes observed in practice.

Or. en

Amendment 266
Alviina Alametsä

Proposal for a regulation
Article 57 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.	4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups. ***The Board shall make sure to actively reach out to and hear representatives from groups, which are more vulnerable to discriminatory effects posed by AI, such as people with disabilities.***

Or. en

Amendment 267
Alviina Alametsä

Proposal for a regulation
Article 59 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a	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.	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***,*** safety ***and environmental*** risks and knowledge of existing standards and legal requirements.

Or. en

Amendment 268
Kosma Złotowski

Proposal for a regulation
Article 59 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. National competent authorities shall satisfy the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (…) on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148.

Or. en

Amendment 269
Kosma Złotowski

Proposal for a regulation
Article 59 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4 b. Any information and documentation obtained by the national competent authorities pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

Amendment 270
Kosma Złotowski

Proposal for a regulation
Article 59 – paragraph 7

Text proposed by the Commission	*Amendment*
7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States ***may*** also establish one central contact point for communication with operators.	7. National competent authorities may provide guidance and advice on the implementation of this Regulation, including to small-scale providers. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted, as appropriate. Member States ***shall*** also establish one central contact point for communication with operators. ***In addition, the central contact point of each Member State should be contactable through electronic communications means.***

Or. en

Amendment 271
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Article 60 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Information contained in the EU database shall be accessible to the public.	3. Information contained in the EU database shall be accessible to the public***, user-friendly, easily navigable and machine-readable***.

Or. en

Amendment 272
Kosma Złotowski

Proposal for a regulation
Article 60 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The EU database shall contain ***personal data only insofar as necessary for collecting and processing*** information ***in accordance with this Regulation. That information shall include the names and contact details of*** natural ***persons who are responsible for registering the system and have the*** legal ***authority to represent the provider***.	4. 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 273
Kosma Złotowski

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 274
Kateřina Konečná

Proposal for a regulation
Article 61 – paragraph 2

Text proposed by the Commission	*Amendment*

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2. ***Post-market monitoring must include continuous analysis of the AI environment, including other devices, software, and other AI systems that will interact with the AI system.***

Or. en

Amendment 275
Kosma Złotowski

Proposal for a regulation
Article 61 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.	2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users ***and end-users*** or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2.

Or. en

Amendment 276
Kosma Złotowski

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission	*Amendment*

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.	1. Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted ***adequate*** access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access***, taking into account the scope of access agreed with the relevant data subjects or data holders***.

Or. en

Amendment 277
Kosma Złotowski

Proposal for a regulation
Article 64 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request***, the*** market surveillance authorities ***shall be granted access to the source code of the AI system***.	2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request***. AI providers or deployers should support*** market surveillance authorities ***with the necessary facilities to carry out testing to confirm compliance***.

Or. en

Amendment 278
Alviina Alametsä

Proposal for a regulation
Article 65 – paragraph 1

Text proposed by the Commission	*Amendment*
1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to ***the*** health ***or*** safety or to the protection	1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to health***,*** safety ***or the environment,*** or to

of fundamental rights of persons are concerned.	the protection of fundamental rights of persons are concerned.

Or. en

Amendment 279
Alviina Alametsä

Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.	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 environment***, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Or. en

Amendment 280
Elsi Katainen, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal

Proposal for a regulation
Article 69 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both,	3. Codes of conduct may be drawn up ***by national, regional or local authorities,*** by individual providers of AI systems or by

including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.	organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

Or. en

Justification

For the AI systems that the national, regional or local authorities themselves use or develop, they should also have the right to draw up codes of conduct. This is also stated in the Committee of the Regions Opinion 'European approach to artificial intelligence - Artificial Intelligence Act (revised opinion)' (SEDE-VII/022).

Amendment 281
Kosma Złotowski

Proposal for a regulation
Article 70 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
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:	1. National competent ***authorities, market surveillance*** authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

Amendment 282
Kosma Złotowski

Proposal for a regulation
Article 70 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. Where the activities of national competent authorities, market

surveillance authorities and bodies notified under the provisions of this Article infringe intellectual property rights, Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of intellectual property rights in full application of Directive 2004/48/EC on the enforcement of intellectual property rights.

Or. en

Amendment 283
Kosma Złotowski

Proposal for a regulation
Article 70 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1 b. Information and data collected by national competent authorities, market surveillance authorities and notified bodies and referred to in Paragraph 1 shall be:
	a) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; further processing for archiving purposes in the public interest, for scientific or historical research purposes or for statistical purposes shall not be considered incompatible with the original purposes ("purpose limitation");
	b) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation');

Or. en

Amendment 284
Kosma Złotowski

Proposal for a regulation
Article 71 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. In cases where administrative fines have been imposed under Article 83 of Regulation 2016/679, no further penalties shall be imposed on operators under the AI Act;

Or. en

Amendment 285
Kosma Złotowski

Proposal for a regulation
Article 72 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the nature, gravity and duration of the infringement and of its consequences;	(a) the nature, gravity and duration of the infringement and of its consequences***, taking into account the number of subjects affected and the level of damage suffered by them***;

Or. en

Amendment 286
Kosma Złotowski

Proposal for a regulation
Article 72 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) the intentional or negligent character of the infringement;

Or. en

Amendment 287
Kosma Złotowski

Proposal for a regulation
Article 72 – paragraph 1 – point a b (new)

Text proposed by the Commission	*Amendment*
	(a b) any relevant previous infringement;

Or. en

Amendment 288
Kosma Złotowski

Proposal for a regulation
Article 72 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) the degree of cooperation with the supervisory authority, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Or. en

Amendment 289
Kosma Złotowski

Proposal for a regulation
Article 72 – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(b b) any action taken by the provider to mitigate the damage suffered by subjects;

Or. en

Amendment 290
Kosma Złotowski

Proposal for a regulation
Article 72 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.

Or. en

Amendment 291
Jörgen Warborn

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 292
Jörgen Warborn

Proposal for a regulation
Article 80 – paragraph 1
Regulation (EU) 2018/858
Article 5

Text proposed by the Commission	*Amendment*
	4 a. 5. The Commission shall, prior to fulfilling the obligation pursuant to paragraph 4, conduct a gap analysis of existing sectoral legislation in the automotive sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principles.

Or. en

Amendment 293
Jörgen Warborn

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 294
Jörgen Warborn

Proposal for a regulation
Article 82 – paragraph 1
Regulation (EU) 2018/858
Article 11

Text proposed by the Commission	*Amendment*
	3 a. 4. The Commission shall, prior to fulfilling the obligation pursuant to paragraph 3, conduct a gap analysis of existing sectoral legislation in the automotive sector to determine the existence of potential gaps relating to Artificial Intelligence therein, and consult relevant stakeholders, in order to avoid duplications and overregulation, in line with the Better Regulation principles.

Or. en

Amendment 295
Kosma Złotowski

Proposal for a regulation
Article 84 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.	***deleted***

Or. en

Amendment 296
Kosma Złotowski

Proposal for a regulation
Article 84 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The Commission shall assess the need for amendment of the list in Annex I every 24months following the entry into force of this Regulation and until the end of the period of the delegation of power.

Or. en

Amendment 297
Kosma Złotowski

Proposal for a regulation
Article 84 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1 b. The Commission shall assess the need for amendment of the list in Annex III every24 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.

Or. en

Amendment 298
Kosma Złotowski

Proposal for a regulation
Article 84 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By [***three*** years after the date of application of this Regulation referred to in Article 85(2)] and every ***four*** years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.	2. By [***two*** years after the date of application of this Regulation referred to in Article 85(2)] and every ***three*** years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

Or. en

Amendment 299
Alviina Alametsä

Proposal for a regulation
Article 84 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. Within [two years after the date of application of this Regulation referred to in Article 85(2)] and every two years thereafter, the Commission shall evaluate the impact and effectiveness of the Regulation with regards to the energy use and other environmental impact of AI systems and evaluate bringing legislation to regulate the energy efficiency of ICT systems in order for the sector to contribute to EU climate strategy and targets.

Or. en

Amendment 300
Kosma Złotowski

Proposal for a regulation

Annex I – title

Text proposed by the Commission	*Amendment*
ARTIFICIAL INTELLIGENCE TECHNIQUES AND ***APPROACHESreferred*** to in Article 3, point 1	ARTIFICIAL INTELLIGENCE TECHNIQUES AND ***APPROACHES referred*** to in Article 3, point 1

Or. en

Amendment 301
Henna Virkkunen

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;***	(b) Logic- and inductive (logic) programming, inference and deductive engines***.***

Or. en

Amendment 302
Kosma Złotowski

Proposal for a regulation
Annex I – point c

Text proposed by the Commission	*Amendment*
(c) Statistical approaches, Bayesian estimation, search and optimization methods.	(c) Statistical approaches, Bayesian estimation, ***, forecasting,*** search and optimization methods.

Or. en

Amendment 303
Kosma Złotowski

Proposal for a regulation
Annex III – paragraph 1 – point 1 – point a

Text proposed by the Commission	*Amendment*
(a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons;	(a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons ***without their consent of being identified***;

Or. en

Amendment 304
Kateřina Konečná

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 water, gas, heating and electricity.	(a) AI systems intended to be used as ***a component, the failure or malfunctioning of which endangers the health,*** safety ***or fundamental rights of persons or the safety of property,*** in the management***,*** operation***, generation and/or supply of the telecom, internet, and financial infrastructure, road, rail, air and water*** traffic***,*** and the ***operation, management an/or*** supply of water, gas, heating***,*** and electricity ***and energy(including nuclear power)***.

Or. en

Amendment 305
Kosma Złotowski

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	(a) AI systems intended to be used as safety components in the management and

operation of road traffic and the supply of water, gas, heating and electricity.	operation of road***, air, railway*** traffic and the supply of water, gas, heating and electricity***, whose failure or malfunctioning would directly cause significant harm to the health, natural environment or safety of natural persons***.

Or. en

Amendment 306
Jörgen Warborn

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 water, gas, heating and electricity.	(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity***, unless these are regulated in harmonisation legislation or sectorial regulation***.

Or. en

Amendment 307
Kosma Złotowski

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;	(a) AI systems intended to be used for ***the sole purpose of*** recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;

Or. en

Amendment 308

Henna Virkkunen

Proposal for a regulation
Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission	*Amendment*
(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and ***behavior*** of persons in such relationships.	(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation ***based on individual behaviour or personal traits or characteristics*** and for monitoring and evaluating performance and ***behaviour*** of persons in such relationships.

Or. en

Amendment 309
Jörgen Warborn

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) AI systems designed for real-time remote biometric identification in publicly accessible locations for law enforcement purposes.

Or. en

Amendment 310
Kosma Złotowski

Proposal for a regulation
Annex IV – paragraph 1 – point 2 – point a

Text proposed by the Commission	*Amendment*
(a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used,	(a) ***provided that no confidential information or trade secrets are disclosed,*** the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained

integrated or modified by the provider;	systems or tools provided by third parties and how these have been used, integrated or modified by the provider;

Or. en

Amendment 311
Kosma Złotowski

Proposal for a regulation
Annex IV – paragraph 1 – point 2 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) ***provided that no confidential information or trade secrets are disclosed,*** the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

Or. en