European Parliament

2019-2024

Committee on Industry, Research and Energy
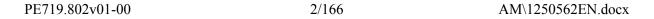
2021/0106(COD)

31.3.2022

AMENDMENTS
127 - 381

Draft opinion
Eva Maydell
(PE719.801v01-00)

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))

United in diversity

AM_Com_LegOpinion

EN

Amendment 127
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

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 *based on ethical principles* in particular for the *design,* development*, deployment*, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety*, environment* and fundamental rights, 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 128
Francesca Donato

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	(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 *and the Charter of Fundamental Rights of the European*

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.

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

Or. it

Amendment 129
Elena Kountoura

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*, environment* and fundamental rights, *as well as consumer protection* and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 130
Eva Kaili, Ivo Hristov

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 *trustworthy* 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*, the environment,* and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 131
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In line with Article 114(2) TFEU, this Regulation does not in any way affect the rights and interests of employed persons. This Regulation is without prejudice to Community law on social policy and national labour law and practice.

Or. en

Amendment 132

EN

Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) Given the significance of AI impact assessments according to the usage of AI applications in the workplace, the EU should consider a corresponding directive with specific provisions for an impact assessment to ensure the protection of the rights and freedoms of workers affected by AI systems through collective agreements or national legislation.

Or. en

Amendment 133
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the	(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is ***trustworthy and*** safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured ***in order to achieve***

free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

trustworthy AI, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Or. en

Amendment 134
Francesca Donato

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal	(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal

EN

market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the **uniform** protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented *or reduced*, by laying down *minimum* uniform obligations for operators and guaranteeing the *organic and consistent* protection of overriding reasons of public interest and of rights of persons throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Or. it

Amendment 135
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The deployment of artificial intelligence applications across sectors will only accelerate in the years to come. The European Union should therefore consider, in separate legislation, the creation of an Artificial Intelligence Adjustment Fund, which could be

beneficial for Member States to cover the accustoming of their labour markets to the new conditions arising from the rapid mass introduction of artificial intelligence systems that could affect specific job sectors.

<div align="right">Or. en</div>

Amendment 136
Francesca Donato

Proposal for a regulation
Recital 3

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

<div align="right">Or. it</div>

Amendment 137
Gianna Gancia, Matteo Adinolfi

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) *Technologies based on artificial intelligence are having a rapid and disruptive impact on the world of work. They have the potential to create new opportunities for gender equality, but at the same time they can reinforce stereotypes, sexism and gender discrimination in the labour market. It is becoming clearer and clearer that automating some tasks will have a greater impact on the female workforce, because a higher number of women are employed in routine work. At the same time, AI can represent a major opportunity for reducing gender inequalities, but only if steps are taken to change regulations and policies to promote the equal representation of men and women in decision-making. Support by European institutions and Member States of an approach designed to encourage women to study STEM subjects will also be vital in combating gender stereotyping.*

Or. it

Justification

Recital 3a should in fact be understood as Recital 4 (new).

Amendment 138
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) *The development of AI applications might bring down the costs and increase the volume of services available, e.g. health services, public transport, Farming 4.0, making them more affordable to a wider spectrum of*

society; that AI applications may also result in the rise of unemployment, pressure on social care systems, and an increase of poverty; in accordance with the values enshrined in Article 3 of the Treaty on European Union, there might be a need to adapt Union AI transformation to socioeconomic capacities, to create adequate social shielding, support education and incentives to create alternative jobs; the establishment of a Union AI Adjustment Fund building upon the experience of The European Globalisation Adjustment Fund (EGF) or the currently developed Just Transition Fund should be considered.

Or. en

Amendment 139
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Furthermore, in order for the Member States to reach their climate targets, European companies should seek to achieve a 'large handprint but small footprint' of artificial intelligence to the environment. To facilitate investments in AI-based analysis and optimisation solutions that can help to achieve the climate goals, this regulation should provide a predictable and proportionate environment for low- risk industrial solutions. To ensure coherence, this requires that AI systems themselves need to be designed sustainably to reduce resource usage and energy consumption, thereby limiting the damage to the environment.

EN

**Amendment 140
Elena Kountoura**

**Proposal for a regulation
Recital 3 a (new)**

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

Or. en

**Amendment 141
Elena Kountoura**

**Proposal for a regulation
Recital 4**

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

environment.

Or. en

Amendment 142
Francesca Donato

Proposal for a regulation
Recital 4

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

Or. it

Amendment 143
Elena Kountoura

Proposal for a regulation
Recital 5

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

EN

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] .

_____

[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).

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] .

_____

[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 144
Josianne Cutajar, Miapetra Kumpula-Natri

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Legislation on artificial intelligence should be accompanied by actions intended to address main barriers hindering the digital transformation of the economy. Such measures should focus on education, upskilling and reskilling workers, fostering investment in R&I, and boosting security in the digital sphere in line with initiatives aimed at achieving the targets of the Digital Decade. Digital transformation should occur in a harmonized manner across regions, paying particular attention to less digitally

Or. en

Amendment 145
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Isabella Tovaglieri, Angelo Ciocca

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 *must* 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 *AI* software, *distinguishing it from more traditional software systems and modelling approaches such as logistic regression and other techniques that are similarly transparent and capable of being explained and interpreted.* In particular, *for the purposes of this Regulation, AI systems should be understood as having* the ability*, on the basis of machine and/or human-based data and inputs, to deduce how to achieve a given set of human-defined objectives through learning, reasoning or modelling* for a given set of human-defined objectives, to generate *specific* outputs *in the form of* content, *for generative AI systems (such as text, video or images), and* predictions, recommendations, or decisions which influence the environment with which the system interacts, in *both* a physical *and* digital dimension. *For the purposes of this AI Regulation,* AI systems can be designed *that must follow an approach with limited explanations and* operate with varying levels *a very high level* of autonomy. *These systems may* be used on *an autonomous* basis or as a component of a product, irrespective of whether the system is physically integrated into the product

EN

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

Or. it

Amendment 146
Miapetra Kumpula-Natri
on behalf of the S&D Group

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***	(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. ***This definition should be understood to exclude tools and software systems that are strictly limited to elementary arithmetic operations on datasets or descriptive data analysis.*** 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

technological developments through the adoption of delegated acts by the Commission to amend that list.

therein (non-embedded). The ***Commission*** should ***take note of the ongoing developments on defining the artificial intelligence within key international organisations such as United Nations Educational, Scientific and Cultural Organization, the Organisation for Economic Cooperation and*** Development, ***International standardization bodies and Council of Europe***.

Or. en

Amendment 147
Elena Kountoura

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	(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 ***(and possibly also hardware)***, 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

EN

adoption of delegated acts by the Commission to amend that list.

technological developments through the adoption of delegated acts by the Commission to amend that list.

Or. en

Amendment 148
Francesca Donato

Proposal for a regulation
Recital 12

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

Or. it

Amendment 149
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) This Regulation should not undermine research and development activity and should respect freedom of

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

Or. en

Amendment 150
Elena Kountoura

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) 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 151
Robert Roos

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*

(12a)   This Regulation shall not restrict research and development activities in the European Union. This is without prejudice to the obligation that all research and development activities must be subject to recognized ethical standards for scientific research under all circumstances.

Or. en

Amendment 152
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.	(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments. *However, with regard to the risk management system for AI systems considered to be high-risk, the EU's harmonisation legislation should focus on the essential requirements and leave their technical implementation to be governed by voluntary product-specific and cutting-edge standards, developed by the stakeholders. It is therefore desirable for European legislation to focus on the desired outcome of the risk management and evaluation systems, and to expressly leave industry the task of designing its systems and tailoring them to its internal operations and structures, particularly by developing cutting-edge standardisation*

systems.

<div align="right">Or. it</div>

Amendment 153
Elena Kountoura

Proposal for a regulation
Recital 13

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

<div align="right">Or. en</div>

Amendment 154
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

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	(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.

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)*, the European Green Deal (The Green Deal) and the Joint Declaration on Digital Rights of the Union (the Declaration)* and should be non-discriminatory and in line with the Union's international trade commitments.

Or. en

Amendment 155
Francesca Donato

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 *to restrict or prevent the use or marketing of systems known to be high-risk*. 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. it

Justification

It must not be possible to use or distribute high-risk systems in the EU where there is no certainty of being able to wholly eliminate any risk to the health and safety of beneficiaries or citizens. For as long as they continue to pose a high risk, it is necessary to adopt the precautionary principle fully and to safeguard fundamental human rights, giving them priority over the rights of industry and commerce.

Amendment 156
Robert Roos

Proposal for a regulation
Recital 13

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

Or. en

Amendment 157
Francesca Donato

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. it

Amendment 158

Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.	(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems. ***With regard to transparency and human oversight obligations, Member States should be able to adopt further national measures to complement them without changing their harmonising nature.***

Or. en

Amendment 159
Robert Roos

Proposal for a regulation
Recital 14

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

requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.

requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems. *However, it is important to distinguish both categories between the person who develops and makes the system available and the person who deploys the AI-system.*

Or. en

Amendment 160
Francesca Donato

Proposal for a regulation
Recital 14

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

Or. it

Amendment 161
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*

	(14a) Without prejudice to tailoring rules to the intensity and scope of the risks that AI systems can generate, or to the specific requirements laid down for high-risk AI systems, all AI systems developed, deployed or used in the Union should respect not only Union and national law but also a specific set of ethical principles that are aligned with the values enshrined in Union law and that are in part, concretely reflected in the specific requirements to be complied with by high-risk AI systems. That set of principles should, inter alia, also be reflected in codes of conduct that should be mandatory for the development, deployment and use of all AI systems. Accordingly, any research carried out with the purpose of attaining AI-based solutions that strengthen the respect for those principles, in particular those of social responsibility and environmental sustainability, should be encouraged by the Commission and the Member States.

Or. en

Amendment 162
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 14 b (new)

Text proposed by the Commission	*Amendment*

	(14b) AI literacy' refers to skills, knowledge and understanding that allows both citizens more generally and developers, deployers and users in the context of the obligations set out in this Regulation to make an informed deployment and use of AI systems, as well as to gain awareness about the

opportunities and risks of AI and thereby promote its democratic control. AI literacy should not be limited to learning about tools and technologies, but should also aim to equip citizens more generally and developers, deployers and users in the context of the obligations set out in this Regulation with the critical thinking skills required to identify harmful or manipulative uses as well as to improve their agency and their ability to fully comply with and benefit from trustworthy AI. It is therefore necessary that the Commission, the Member States as well as developers and deployers of AI systems, in cooperation with all relevant stakeholders, promote the development of AI literacy, in all sectors of society, for citizens of all ages, including women and girls, and that progress in that regard is closely followed.

Or. en

Amendment 163
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights	(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy*, gender*

EN

of the child.

equality and the rights of the child.

Or. en

Amendment 164
Francesca Donato

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and ***should*** be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.	(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and ***absolutely must*** be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.

Or. it

Amendment 165
Francesca Donato

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and	(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and

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

people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the provider or the user.

Or. it

Amendment 166
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16)　The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the behaviour of a person and in a manner that causes or is likely to cause harm to that or another person. The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are outside of the control of the	(16)　The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby *economic,* physical or psychological harms are likely to occur, should be forbidden*. This limitation should be understood to include neuro-technologies assisted by AI systems that are used to monitor, use, or influence neural data gathered through brain-computer interfaces for pecuniary purposes*. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of children and people due to their age, physical or mental incapacities. They do so with the intention to materially distort the

EN

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

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

Or. en

Amendment 167
Elena Kountoura

Proposal for a regulation
Recital 16

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

amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research.

ethical standards for scientific research.

Or. en

Amendment 168
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 16

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

Or. en

To bring the recital in line with amendments proposed to Art 5, paragraph 1 regarding the uses of neurotechnology without consent.

Amendment 169
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

Proposal for a regulation
Recital 16

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

Or. en

Amendment 170

Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation
Recital 16

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

Or. en

Amendment 171
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) AI systems providing social scoring of natural persons *for general purpose by*	(17) AI systems providing social scoring of natural persons*, assessing the risk of*

EN

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

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

Or. en

Justification

To bring the recital in line with amendments proposed to Art 5, paragraph 1 regarding the use of social scoring by the private sector, police profiling, and biometric and biometrics-based categorisation.

Amendment 172
Francesca Donato

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality	(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality

and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems **should** be **therefore** prohibited.

and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. *It is therefore extremely important for* such AI systems *to* be prohibited.

Or. it

Amendment 173
Elena Kountoura

Proposal for a regulation
Recital 17

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

gravity of their social behaviour. Such AI systems should be therefore prohibited.

systems should be therefore prohibited.

Or. en

Amendment 174
Josianne Cutajar, Miapetra Kumpula-Natri

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) The use of Artificial Intelligence in work can be beneficial to both the management and operations of an enterprise, supporting workers in their tasks and improving safety on the workplace. Still, Artificial Intelligence systems applied to digital labour platforms, platforms for the management of workers, including in the field of transport, can entail risks of unjust/unnecessary social scoring, rooted in biased data sets, which can lead to violation of workers and fundamental rights. This Regulation should therefore aim at protecting the rights of workers managed by digital labour platforms and promote transparency, fairness and accountability in algorithmic management, to ensure workers are aware of how the algorithm works, which personal data is issued and how their behaviour affects decisions taken from the automated system.

Or. en

Amendment 175
Elena Kountoura

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

Or. en

Amendment 176
Eva Kaili, Ivo Hristov

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	(18) The use of AI systems for biometric ***or biometrics-based*** 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.

corrections carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities.

Or. en

Amendment 177
Eva Kaili, Ivo Hristov

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,*	(19) The use of *biometric or biometrics-based* systems *that can be used for monitoring large numbers of persons, be it in public or private spaces,* should therefore be prohibited.

some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

_____

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

Or. en

Justification

To bring the recital in line with amendments proposed to Art 5, paragraph 1 regarding biometric and biometrics-based data identification of natural persons.

Amendment 178
Elena Kountoura

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

EN

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 possible negative consequences.*

_____

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

natural persons or of a terrorist attack;

Or. en

Amendment 179
Francesca Donato

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 possible negative consequences.

(19)   The use of those systems for the purpose of law enforcement *must* therefore be prohibited, *as a matter of principle and without any general exceptions. Only in exceptional cases and on the basis of decisions taken by the judicial authority competent on the matter and in the territory of one of the Member States, within the scope of the following* three exhaustively listed and narrowly defined situations, *may the use of such systems be permitted to the extent and for the time period* strictly necessary to achieve *an extremely* substantial public interest, the importance of which *is considered by the relevant judicial authority to prevail over* 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 *ten* years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a

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

_____ _____

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

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. it

Amendment 180
Francesca Donato

Proposal for a regulation
Recital 20

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

Amendment 181
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 20

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

Or. en

Amendment 182
Elena Kountoura

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) In order to ensure that those	(20) In order to ensure that those

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

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

Or. en

Amendment 183
Elena Kountoura

Proposal for a regulation
Recital 21

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

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

Or. en

Amendment 184
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 21

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

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

Or. en

Amendment 185
Francesca Donato

Proposal for a regulation
Recital 21

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

Or. it

Amendment 186
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 22

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

Or. en

Amendment 187
Eva Kaili, Ivo Hristov

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,	*deleted*

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

Or. en

Amendment 188
Francesca Donato

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	(23) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation

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

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

Or. it

Amendment 189
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) Any processing of biometric data	(24) Any processing of biometric data

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

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

Or. en

Amendment 190
Francesca Donato

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) 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 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.

Or. it

Amendment 191
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

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

Or. en

Amendment 192
Elena Kountoura

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	(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*.

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*, but also on the environment, democracy and the rule of law* in the Union.

Or. en

Amendment 193
Francesca Donato

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk.	(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments *and always under close supervision by human intelligence, with the ability to stop any of their actions quickly, if necessary*. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate *and never totally independent of human control*. The

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

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

Or. it

Amendment 194
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) AI systems could produce adverse outcomes to health and safety of persons,	(28) AI systems could produce adverse outcomes to health and safety of persons,

in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection

in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, *gender equality, education,* consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high

enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.

level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons *or to the environment, due to the extraction and consumption of natural resources, waste and the carbon footprint*.

Or. en

Amendment 195
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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] , 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	(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.

and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts.

In addition, effective standardisation rules are needed to make the requirements of this Regulation operational. The European institutions, and first and foremost the Commission, should, together with enterprises, identify the AI sectors where there is the greatest need for standardisation, to avoid fragmentation of the market and maintain and further strengthen the integration of our European Standardisation System (ESS) within the International Standardisation System (ISO, IEC).

_____

[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

_____

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

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

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

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

[43]Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L

138, 26.5.2016, p. 44).

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

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

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

EN

347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

Or. it

Amendment 196
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission	*Amendment*
	(29a) To demonstrate that the characteristics of a high-risk AI system conform to the requirements set out in Chapter 2 of Title III, it must be possible to conduct internal controls and use harmonised standards based on agreement. It is desirable for the European institutions, and first and foremost the Commission, to do more to promote alignment with existing international standardisation activities and with the certifications issued as part of the EU information security scheme. However, unlike the procedure to assess product conformity, where assessment infrastructure is in place, the relevant competence for auditing autonomous AI systems is still being developed. Moreover, because of the specific technological features of AI, it is possible that the competent authorities may encounter difficulties in verifying the conformity of some AI systems with existing legislation. It is therefore necessary for conformity assessment mechanisms to be developed with flexibility, so that due account may be taken of the infrastructure gaps, and disparities in application may be avoided in the single market.

Or. it

EN

Amendment 197
Francesca Donato

Proposal for a regulation
Recital 30

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

Or. it

Amendment 198
Francesca Donato

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	(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

EN

the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and *its probability of occurrence* and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and *the possibility that it may occur* and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems.

Or. it

Amendment 199
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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. 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 *supervision*.

Or. it

Amendment 200
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*

(35)   AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right ***not to*** be discriminated against and perpetuate historical patterns of discrimination.

(35)   AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed**, *developed*** and used, such systems may violate the right to education and training as well as the right ***to gender equality and to not*** be discriminated against and perpetuate historical patterns of discrimination.

Or. en

Amendment 201
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*

(36)   AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through

(36)   AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact ***the health, safety and security rules applicable in their work and at their workplaces and*** future career prospects and livelihoods of these persons. Relevant work-related contractual

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

relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy. *In this regard, specific requirements on transparency, information and human oversight should apply. Trade unions and workers representatives should be informed and they should have access to any documentation created under this Regulation for any AI system deployed or used in their work or at their workplace.*

Or. en

Amendment 202
Elena Kountoura

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be *classified as high-risk*, since those systems may appreciably impact future career	(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be *prohibited*, since those systems may appreciably impact *the health, safety and*

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

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

Or. en

Amendment 203
Francesca Donato

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	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and

telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. ***Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use.*** Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. ***Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons.*** Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. it

Amendment 204
Francesca Donato

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

(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, *political orientation or personal opinions,* or create new forms of discriminatory impacts. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they 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,

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.

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

Or. it

Amendment 205
Elena Kountoura

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	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of

discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be *classified as high-risk*. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a *high* risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

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 *prohibited*. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a *an unacceptable* 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 206
Francesca Donato

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*

(38)   Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection,

(38)   Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection,

investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. *AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.*

Or. it

Amendment 207
Elena Kountoura

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to *classify as high-risk a number of* AI	(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented *and where a redress procedure is not foreseen*. It is therefore

systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those *high-risk AI* systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person*, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings*, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences*, as well as for crime analytics regarding natural persons*. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be *considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences*.

appropriate to *prohibit some* AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress*, including the availability of redress-by-design mechanisms and procedures*. In view of the nature of the activities in question and the risks relating thereto, those *prohibited* systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons, or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups, for profiling in the course of detection, investigation or prosecution of criminal offences. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be *included in such a ban*.

Or. en

Amendment 208
Elena Kountoura

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*

(39)   AI systems used in migration, asylum and border control management affect people who are often in particularly

(39)   AI systems used in migration, asylum and border control management affect people who are often in particularly

vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to *classify as high-risk* AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; *for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status.* AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation.

vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to *prohibit* AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; *Other* AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation.

---

[49] Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of

---

[49] Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of

13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. en

Amendment 209
Francesca Donato

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) To ***mitigate*** the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements ***should apply***, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.	(42) To ***eliminate*** the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, ***the use of these systems must be prohibited, and only systems known to be medium/low-risk must be permitted to be placed on the market, applying to the latter*** certain mandatory requirements, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.

Or. it

Amendment 210
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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	(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 ***supervision***, 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.

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.

Or. it

Amendment 211
Miapetra Kumpula-Natri
on behalf of the S&D Group

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	(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*, with specific attention to the mitigation of possible biases in the datasets, that might lead to risks to fundamental rights or discriminatory outcomes for the persons affected by the high-risk AI system*. In particular, training, validation and testing data sets should take into account, to the extent required in the

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.

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

Or. en

Amendment 212
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,	(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

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.

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 213
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access	(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission *, competitive and fair European data economy structured around interoperable data intermediation services* and the facilitation of data sharing between businesses and with government

to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

Or. en

Amendment 214
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk	(46) Having *comprehensible* information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation *and to allow users to make informed and autonomous decisions about their use*. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training,

management system. The technical documentation should be kept up to date.

testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Or. en

Amendment 215
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a *certain* degree of transparency should be required for high-risk AI systems. Users should be able to interpret the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.	(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a *sufficient* degree of transparency should be required for high-risk AI systems. Users should be able to interpret the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate. ***The same applies to AI systems with general purposes that may have high-risk uses that are not forbidden by their developer. In such cases, sufficient information should be made available allowing deployers to carry out tests and analysis on performance, data and usage. The systems and information should also be registered in the EU database for stand-alone high-risk AI systems foreseen in Article 60 of this Regulation.***

Or. en

Amendment 216
Patrizia Toia, Miapetra Kumpula-Natri

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. Users should be able to interpret the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.	(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency **and comprehensibility** should be required for high-risk AI systems **and their algorithms**. Users should be able to interpret **both the algorithmic decision-making and** the system output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.

Or. en

Amendment 217
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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	(48) ***Human supervision must remain the basic ethical principle for the development and distribution of high-risk AI, since it guarantees transparency, confidentiality and protection of data and safeguarding against discrimination. However, it is vital to maintain a balance between meaningful human supervision and the efficiency of the system, in order not to compromise the benefits offered by these systems in sectors such as information security analysis, threat analysis and incident response processes.*** High-risk AI systems should be designed

oversight has been assigned have the necessary competence, training and authority to carry out that role.

and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human *supervision* 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 *supervision* has been assigned have the necessary competence, training and authority to carry out that role.

Or. it

Amendment 218
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

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 *have agency over them by being able to* oversee *and control* 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 *and at the very least where decisions based solely on the automated processing enabled by such systems produce legal or otherwise significant effects*, 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 219
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the *generally* acknowledged state of the art. *The* level of accuracy and accuracy metrics should be communicated to the users.	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the acknowledged state of the art. *Accuracy metrics and their expected level must be defined with the primary objective to mitigate risks and negative impact of the AI system to individuals and the society at large, The expected* level of accuracy and accuracy metrics should be communicated to the users. *The declaration of accuracy metrics cannot however be considered proof of future levels but relevant methods need to be applied to ensure sustainable levels during use*

Or. en

Amendment 220
Elena Kountoura

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) High-risk AI systems should perform consistently throughout their	(49) High-risk AI systems should perform consistently throughout their

lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the users.

lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated *in a clear, transparent, easily understandable and intelligible way* to the users.

Or. en

Amendment 221
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the users.	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated *in an intelligible manner* to the *deployers and* users.

Or. en

Amendment 222
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 50

Text proposed by the Commission	*Amendment*
(50) The technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors,	(50) The technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors,

faults, inconsistencies, unexpected situations) as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect the fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system.

faults, inconsistencies, unexpected situations) as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect the fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system. ***Users of the AI system should take steps to ensure that the possible trade-off between robustness and accuracy does not lead to discriminatory or negative outcomes for minority subgroups.***

Or. en

Amendment 223
Elena Kountoura

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

infrastructure.

Or. en

Amendment 224
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 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.	(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 confidentiality* attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Or. en

Amendment 225
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) In the light of the complexity of the	(60) In the light of the complexity of the

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

artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should *ensure, through technical means, the transparency and auditability for* providers and users to enable their compliance with the obligations under this Regulation and *cooperate and assist* competent authorities established under this Regulation *in its enforcement*.

Or. en

Amendment 226
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient.	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should be a means for providers to demonstrate conformity with the requirements of this Regulation. *In addition to technical details, the standardisation process should also include an assessment of risks to fundamental rights, the environment, societal risks and other sociotechnical considerations, such as how a given technology might interact with other technologies. The standardisation process should be transparent in terms of legal and natural persons participating the standardisation activities.* However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they

are insufficient. *In developing these common specifications Commission should involve views of relevant stakeholders, in particular when the common specifications address specific fundamental rights concerns. In particular, the Commission should adopt common specifications setting out how risk management systems give specific consideration to impact on children.*

_____

⁵⁴ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

_____

⁵⁴ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Or. en

Amendment 227
Tsvetelina Penkova

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as

EN

regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification. *The conformity assessment requirements as defined by this Regulation shall not apply for firmware and software updates developed by the product manufacturer.*

Or. en

Amendment 228
Francesca Donato

Proposal for a regulation
Recital 68

	Text proposed by the Commission	Amendment

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

deleted

Or. it

Amendment 229
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation

Recital 68

Text proposed by the Commission	*Amendment*
(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.	(68) Under certain conditions, rapid availability of innovative technologies may be crucial for health and safety of persons and for society as a whole. It is thus appropriate that under exceptional *and ethically justified* reasons of public security or protection of life and health of natural persons and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

Or. en

Amendment 230
Elena Kountoura

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers *and users* of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission*. Certain AI systems listed in Article 52(1b) and (2) and uses thereof shall be registered in the EU database. In order to facilitate this, users shall request information listed in Annex VIII point 2(g) from providers of AI systems. Any uses of AI systems by public authorities or on their behalf shall also be registered in*

the Commission and an independent audit report.

the EU database. In order to facilitate this, public authorities shall request information listed in Annex VIII point 3(g) from providers of AI systems. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. *In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the European Accessibility Act.*

---

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

---

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

Or. en

Amendment 231
Elena Kountoura

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*
(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to	(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to

specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use *or where the content forms part of an evidently creative, artistic or fictional cinematographic or analogous work*. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose *in an appropriate, clear and transparent manner* that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 232
Francesca Donato

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*

(70)   Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. *In certain circumstances,* the use of these systems should therefore be subject to specific transparency obligations without

(70)   Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. The use of these systems should therefore be subject to specific transparency obligations without prejudice to the

prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system*, unless this is obvious from the circumstances and the context of use*. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. it

Amendment 233
Patrizia Toia, Miapetra Kumpula-Natri

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*

(70)	Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use.

(70)	Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use.

Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose *in an appropriate, clear and visible manner* that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 234
Eva Kaili, Ivo Hristov

Proposal for a regulation
Recital 70

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

accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 235
Elena Kountoura

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 *and fully controlled* space for experimentation, while ensuring responsible innovation and integration of appropriate *ethical* safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. *Regulatory sandboxes involving activities that may impact health, safety and fundamental rights, democracy and rule of law or the environment shall be developed in accordance with redress-by-design principles. Any significant risks identified during the development and testing of*

such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. The legal basis of such sandboxes should comply with the requirements established in the existing data protection framework and should be consistent with the Charter of fundamental rights of the European Union.

Or. en

Amendment 236
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 237
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

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 *and ethically justified* safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Or. en

Amendment 238
Francesca Donato

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Artificial intelligence is a rapidly	(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.

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 *advised* 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.

Or. it

Amendment 239
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory *supervision* 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 *supervision* before these systems are placed on the market or

into service.

otherwise put into service.

Or. it

Amendment 240
Elena Kountoura

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a *strictly* controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation*, as well as with the Charter of fundamental rights of the European Union and the General Data Protection Regulation*; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, *to provide safeguards needed to build trust and reliance on AI systems* and to accelerate access to markets, including by removing barriers for *the public sector,* small and medium enterprises (SMEs) and start-ups*; to contribute to the development of ethical, socially responsible and environmentally sustainable AI systems*. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI

following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Or. en

Amendment 241
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' *oversight* and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' *supervision* and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. ***To permit effective***

implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

participation by these categories in regulatory sandboxes, compliance costs must be kept to an absolute minimum. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Or. it

Amendment 242
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory	(72) The objectives of the regulatory

sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups*; to contribute to the development of ethical, socially responsible and environmentally sustainable AI systems, in line with the ethical principles outlined in this Regulation*. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and

Article 57 of Directive 2016/680.

Amendment 243
Josianne Cutajar, Miapetra Kumpula-Natri

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups *as well as to contribute to achieving the targets on AI as set in the Policy Programme "Path to the Digital Decade"*. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in

following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Or. en

Amendment 244
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' *oversight* and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' *supervision* and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the

relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Or. it

Amendment 245
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 72 a (new)

Text proposed by the Commission	*Amendment*
	(72a) It is desirable for the establishment of regulatory sandboxes, which is currently left to the discretion of Member States, to be made obligatory, with properly established criteria, to ensure both the effectiveness of the system and easier access for enterprises, particularly SMEs. It is also necessary for research enterprises and institutions to be involved in developing the conditions for the

creation of regulatory sandboxes.

Or. it

Amendment 246
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

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 *AI literacy,* awareness raising and information communication. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.

Or. en

Amendment 247
Elena Kountoura

Proposal for a regulation

EN

Recital 74

Text proposed by the Commission	*Amendment*

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

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

Or. en

Amendment 248
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 74

Text proposed by the Commission	*Amendment*

(74)   In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level should possibly

(74)   In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level *and the national*

contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

cybersecurity agencies should possibly contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

Or. it

Amendment 249
Eva Kaili, Ivo Hristov

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 requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence.	(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. *The Board should work towards establishing a European Regulatory Agency for Artificial Intelligence in line with the provisions of Article 56(3).*

Or. en

Amendment 250
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

Proposal for a regulation

Recital 76 a (new)

Text proposed by the Commission	*Amendment*
	(76a) An AI advisory council ('the Advisory Council') should be established as a sub-group of the Board consisting of relevant representatives from industry, research, academia, civil society, standardisation organisations, relevant common European data spaces, and other relevant stakeholders, including social partners, where appropriate depending on the subject matter discussed, representing all Member States to maintain geographical balance. The Advisory Council should support the work of the Board by providing advice relating to the tasks of the Board. The Advisory Council should nominate a representative to attend meetings of the Board and to participate in its work.

Or. en

Amendment 251
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis	(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy *socially responsible and environmentally sustainable* artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems. Providers should also

additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

Or. en

Amendment 252
Francesca Donato

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should ***be encouraged to*** create codes of conduct intended to foster the ***voluntary*** application of the ***mandatory*** requirements applicable to high-risk AI systems. Providers should also be encouraged to apply ***on a voluntary basis*** additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI	(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should ***nonetheless*** create codes of conduct intended to foster the application of the requirements applicable to high-risk AI systems. Providers should also be encouraged to apply additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access

development, including on data access infrastructure, semantic and technical interoperability of different types of data.

infrastructure, semantic and technical interoperability of different types of data.

Or. it

Amendment 253
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

Proposal for a regulation
Recital 86 a (new)

Text proposed by the Commission	*Amendment*
	(86a) In order to ensure uniform conditions for the implementation of this Regulation, it shall be accompanied by the publication of guidelines to help all stakeholders to interpret key concepts covered by the Regulation, such as prohibited or high-risk AI cases and the precise means and implementation rules of the Regulation by national competent authorities;

Or. en

Amendment 254
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Recital 89 a (new)

Text proposed by the Commission	*Amendment*
	(89a) As things currently stand, the AI sector has a strategic international dimension. In order to achieve the objectives and ambitions set out in this Regulation and strengthen the European approach to AI internationally, it is a matter of urgency that thinking in this area, including as a result of of this

legislation, should not remain solely within the European Union. If the EU wishes to be at the forefront of creating democratic and inclusive regulation that respects the rights of individuals, including those outside Europe's borders, it should seek to be a benchmark in this sphere for non-EU countries too. That would serve to safeguard the competitiveness of the principal actors of the market and spread practices similar to those in this Regulation on a global scale. This Regulation's effectiveness would be strengthened if the European Union were able to play a key role at international level too.

Or. it

Justification

Recital 89a should in fact be seen as Recital 90 (new).

Amendment 255
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;	(a) harmonised rules for the placing on the market, the putting into service and the use of **human-centric and trustworthy** artificial intelligence systems ('AI systems') in the Union;

Or. en

Amendment 256
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

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

Text proposed by the Commission	*Amendment*
(a) harmonised rules for the ***placing on the market, the putting into service*** and the use of artificial intelligence systems ('AI systems') in the Union;	(a) harmonised rules for the ***development, deployment*** and the use of artificial intelligence systems ('AI systems') in the Union;

Or. en

Amendment 257
Francesca Donato

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

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

Or. it

Amendment 258
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	When justified by significant risks to fundamental rights of persons, Member States may introduce specific regulatory solutions ensuring a higher level of protection of persons than offered in this Regulation.

Or. en

Amendment 259

Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

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

Text proposed by the Commission	*Amendment*
(a) *providers* placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country;	(a) *'developer'* placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country *or that adapts a general purpose AI system to a specific purpose and use*;

Or. en

Amendment 260
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

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

Text proposed by the Commission	*Amendment*
(b) users of AI systems *located within* the Union;	(b) users of AI systems *using the AI system in* the Union ;

Or. en

Amendment 261
Francesca Donato

Proposal for a regulation
Article 2 – paragraph 3

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

Or. it

EN

Amendment 262
Tsvetelina Penkova

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

Text proposed by the Commission	*Amendment*
	5a.　　This Regulation shall not apply to AI systems, including their output, specifically developed and put into service for the sole purpose of scientific research and development in the context of academic R&D projects. The Commission may adopt delegated acts that may clarify the further exemptions.

Or. en

Amendment 263
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	5a.　　This Regulation shall not affect research activities regarding AI systems insofar as such activity does not lead to or entail placing an AI system on the market or putting it into service. These research activities shall not violate the fundamental rights of the affected persons.

Or. en

Amendment 264
Henna Virkkunen

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

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

Or. en

Amendment 265
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
	5a. This Regulation shall facilitate the exchange of data used solely for academic and scientific endeavours in a safe scientific space.

Or. en

Amendment 266
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	5b. 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 267
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	5b. This Regulation shall be without prejudice to Regulation (EU) 2016/679.

Or. en

Amendment 268
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	5c. This Regulation shall be without prejudice to Union and national laws on social policies.

Or. en

Amendment 269
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	5d. This Regulation shall be without prejudice to national labour law and practice, that is any legal or contractual provision concerning employment conditions, working conditions, including health and safety at work and the relationship between employers and

workers, including information, consultation and participation.

Or. en

Amendment 270
Elena Kountoura

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 *(and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal; AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions; AI systems can be* developed with one or more of the techniques and approaches listed in Annex I;

Or. en

Amendment 271
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
(1) 'artificial intelligence system' (AI	(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;

system) means *a system that*

(i) receives machine-based and/or human-based data and inputs

(ii) adopts an approach with *limited explanations that infers how to achieve* a given set of human-defined objectives *through learning, reasoning or modelling implemented using the techniques and approaches listed in Annex I, and*

(iii) generates outputs *with a very high level of autonomy in the form of* content *(generative AI systems)*, predictions, recommendations, or decisions influencing the environments *it interacts* with;

Or. it

Amendment 272
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 273
Eva Kaili, Ivo Hristov

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 *any* software *or machine-based system* 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, *make* predictions, recommendations, or decisions influencing *real or virtual environments.* the environments they interact with*. AI systems can be designed with varying levels of autonomy.*

Or. en

Justification

This aligns the definition of "Artificial Intelligence" in the AI Act with that of the OECD, contributing towards a more clear and harmonised regulatory landscape for AI.

Amendment 274

Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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

Text proposed by the Commission	*Amendment*
(1) 'artificial intelligence system' (AI system) means *software that is* developed with one or more of the techniques and approaches listed in Annex I *and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with*;	(1) 'artificial intelligence system' (AI system) means *a machine-based system that can for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments; AI systems can be designed to operate with varying levels of autonomy and can be* developed with one or more of the techniques and approaches listed in Annex I;

Or. en

Justification

The definition in Article 3.1 should be in line with the broadly recognised definition from the recommendation of the Organisation for Economic Co-Operation and Development (OECD/LEGAL/0449).

Amendment 275
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

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 human-defined objectives, *indispensably with some degree of autonomy,* generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Amendment 276
Francesca Donato

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 *an automated system or* 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;

Or. it

Amendment 277
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 *machine-based system that can, with a varying levels of autonomy and* for a given set of objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the *real or virtual* environments they interact with;

Or. en

Amendment 278
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
	(a) *'AI system used in an advisory capacity' means*
	an AI system in which the final decision is taken by a human.

Or. it

Amendment 279
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
	(b) *'AI system with decision-making capacity' means*
	an AI system with the capacity to model decisions in a repeatable manner, without human supervision.

Or. it

Amendment 280
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	(1a) *'autonomy' means an AI system that operates by interpreting certain input and by using a set of pre-determined*

objectives, without being limited to such instructions, despite the system's behaviour being constrained by, and targeted at, fulfilling the goal it was given and other relevant design choices made by its developer;

Or. en

Amendment 281
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 282
Tsvetelina Penkova

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

Text proposed by the Commission	*Amendment*
(2) 'provider' means a natural or legal	(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;

person, public authority, agency or other body that develops an AI system or that has an AI system developed *or places that system* on the market or *puts* it into service under its own name or trademark, whether for payment or free of charge;

Or. en

Amendment 283
Robert Roos

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) '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*, this includes research activities to the extent that they are conducted in accordance with generally accepted ethical standards*;

Or. en

Amendment 284
Tsvetelina Penkova, Romana Jerković, Miapetra Kumpula-Natri

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

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

Or. en

Amendment 285
Robert Roos

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

Text proposed by the Commission	*Amendment*
	(4a) *'end-user' means the natural or legal person who interacts with the results produced by the AI-system;*

Or. en

Amendment 286
Lina Gálvez Muñoz, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation
Article 3 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(8) 'operator' means the ***provider***, the user, the authorised representative, the importer and the distributor;	(8) 'operator' means the ***developer, the deployer***, the user, the authorised representative, the importer and the distributor;

Or. en

Amendment 287
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) *'deployer' means any natural or legal person, public authority, agency or other body putting into service an AI system developed by another entity without substantial modification, or using*

an AI system under its authority,

Or. en

Amendment 288
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 materials and statements, as well as in the technical documentation;	(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*. General purpose AI systems shall not be considered as having an intended purpose within the meaning of this Regulation*;

Or. en

Amendment 289
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 3 – paragraph 1 – point 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) 'general purpose AI system' means an AI application that performs generally applicable functions such as image or speech recognition, audio or video generation, pattern detection, question answering, and translation, and is largely customizable;

Or. en

Amendment 290
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 which fulfils a safety function for that product or system *and* the failure or malfunctioning of which endangers the health and safety of persons or property;

Or. en

Amendment 291
Tsvetelina Penkova, Romana Jerković, Miapetra Kumpula-Natri

Proposal for a regulation
Article 3 – paragraph 1 – point 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) 'information security component of a product or system' means a component of a product of a system which has been specifically designed to fulfil security function for that product or system against cyber incidents, disruptions and/ or attacks;

Or. en

Amendment 292
Tsvetelina Penkova, Romana Jerković, Miapetra Kumpula-Natri

Proposal for a regulation
Article 3 – paragraph 1 – point 14 b (new)

Text proposed by the Commission	*Amendment*

(14b) *'information security product or system' means a product or of a system which has been specifically designed to fulfil a security function against cyber incidents, disruptions and/ or attacks;*

Or. en

Amendment 293
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
	(33a) *'biometrics-based data' means personal data resulting from specific technical processing related to physical, physiological or behavioural signals or characteristics of a natural person, such as facial expressions, movements, pulse frequency, voice, keystrokes or gait, which may or may not allow or confirm the unique identification of a natural person;*

Or. en

Justification

Complements the definition of 'biometric data', which in line with the GDPR, covers "strong" biometric identifiers used mostly in first-generation biometric technologies. The 2021 Biometric Recognition and Behavioural Detection study, commissioned by the European Parliament, notes that modern biometric technologies combine "strong" and "weak" biometric identifiers to overcome poor data quality or missing data and enable more efficient surveillance and more detailed profiles. Including a definition of "biometrics-based data" strengthens the provisions against the use of AI for mass surveillance (see corresponding amendment in Article 5).

Amendment 294
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 3 – paragraph 1 – point 34

Text proposed by the Commission	*Amendment*
(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions **or** intentions of natural persons on the basis of their biometric data;	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions**, thoughts, memories,** intentions**, or other mental states** of natural persons on the basis of their biometric **or biometrics-based** data;

Or. en

Justification

The rapid development of AI and neurotechnology (e.g. brain-computer interfaces) already allows researchers and developers of gadgets and wearable devices the possibility to access certain components of mental information. It is thus important to adapt the relevant definitions to prevent the misuse of technology and safeguard the neurorights of European citizens, and to provide developers and providers of said technologies with more legal clarity when complying with the Artificial Intelligence Act.

Amendment 295
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 3 – paragraph 1 – point 34

Text proposed by the Commission	*Amendment*
(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions**, thoughts,** or intentions of natural persons on the basis of their biometric **or biometrics-based** data;

Or. en

Amendment 296
Eva Kaili, Ivo Hristov

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, hair colour, eye colour, tattoos, ethnic origin, *health, mental ability, behavioural traits,* or sexual or political orientation, on the basis of their biometric *or biometrics-based* data;

Or. en

Amendment 297
Elena Kountoura

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, hair colour, eye colour, tattoos, *health, personal traits,* ethnic origin or sexual or political orientation, on the basis of their biometric data;

Or. en

Amendment 298
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 3 – paragraph 1 – point 35 a (new)

Text proposed by the Commission	*Amendment*
	(35a) 'biometric inferences' means conclusions with regards to permanent or long-term physical, physiological, or behavioural characteristics of a natural person, on the basis of biometrics, biometrics-based data, or other personal

data;

Or. en

Amendment 299
Elena Kountoura

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, might have led or might lead to any of the following:

Or. en

Amendment 300
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 301
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López

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

Text proposed by the Commission	Amendment
(a) the death of a person or serious damage to a person's health, to property or the environment,	(a) the death of a person or serious damage to a person's *fundamental rights,* health, to property or the environment, *to democracy or the democratic rule of law,*

Or. en

Amendment 302
Elena Kountoura

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

Text proposed by the Commission	Amendment
(a) the death of a person or serious damage to a person's health, *to* property or the environment,	(a) the death of a person or serious damage to a person's *fundamental rights,* health, *safety or* property*, to democracy, the rule of law* or the environment,

Or. en

Amendment 303
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

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

Text proposed by the Commission	Amendment
	(aa) 'AI literacy' means the skills, knowledge and understanding regarding AI systems that are necessary for compliance with and enforcement of this Regulation

Or. en

Amendment 304
Henna Virkkunen

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

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

Or. en

Amendment 305
Elena Kountoura

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

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

Or. en

Amendment 306
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(bb) breach of obligations under Union law intended to protect personal data;

Or. en

Amendment 307
Henna Virkkunen

EN

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

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

Or. en

Amendment 308
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(bc) serious damage to the environment;

Or. en

Amendment 309
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
	(44a) 'Systems for identifying and categorising behaviour and cognitive distortions of natural persons' means AI systems designed to be used for emotional calculation and psychographic analysis applications, Machine Learning and Affective Computing applications that use sensitive data from different sources, such as wearable smart devices, sensors, cameras or a person's interactions on the internet, and that are able to evaluate and use emotions, psychological conditions

and behavioural characteristics such as values and beliefs with the aim of assessing and using the cognitive distortions of natural persons. This includes, among other things, the application of Sentiment Analysis techniques and AI Nudging and Sludging.

Or. it

Justification

Recital 441a should in fact be understood as Recital 45 (new).

Amendment 310
Robert Roos

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

Text proposed by the Commission	Amendment
	(44a) 'deep fake' means manipulated or synthetic audio and/or visual material that gives an authentic impression, in which events appear to be taking place, which never happened, and which has been produced using techniques in the field of artificial intelligence, including machine learning and deep learning, without the user, or end-user being aware that the audio and/or visual material has been produced using artificial intelligence;

Or. en

Amendment 311
Henna Virkkunen

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

Text proposed by the Commission	Amendment
	(44a) '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 312
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(44a) 'deep fake' means generated or manipulated image, audio or video content produced by an AI system that appreciably resembles existing persons, objects, places or other entities or events and falsely appears to a person to be authentic or truthful;

Or. en

Amendment 313
Henna Virkkunen

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

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

Or. en

Amendment 314

Elena Kountoura

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

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

Or. en

Amendment 315
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	(44c) '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 316
Elena Kountoura

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

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

Or. en

EN

Amendment 317
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(44d) 'public interest organisation' means a not-for-profit body, organisation or association which has been properly constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest;

Or. en

Amendment 318
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(44e) 'redress by design' means technical mechanisms and/or operational procedures, established from the design phase, in order to be able to effectively detect, audit, rectify the consequences and implications of wrong predictions by an AI system and improve it.

Or. en

Amendment 319
Francesca Donato

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	*deleted*

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. it

Amendment 320
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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 321
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	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

techniques and approaches listed therein.

developments on the basis of characteristics that are similar to the techniques and approaches listed therein.

Or. en

Amendment 322
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

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 that causes or is likely to cause that person or another person physical or psychological harm *that could be predicted with due diligence*;

Or. en

Amendment 323
Jordi Solé
on behalf of the Greens/EFA Group

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 techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person*, economic,* physical or psychological harm;

Justification

Competition law already recognises that particular practices lead to an unacceptable distortion of the markets, and AI has the potential to accentuate such imbalances. Therefore safeguards against practise that lead to economic harm are needed.

Amendment 324
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

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

Text proposed by the Commission	*Amendment*
(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm ***that could be predicted with due diligence***;

Or. en

Amendment 325
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of ***children, or*** a specific group of persons due to their age, physical or mental disability, in order to materially distort the

pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Amendment 326
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission	*Amendment*
(c) the placing on the market, putting into service or use of AI systems *by public authorities or on their behalf* for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:	(c) the placing on the market, putting into service or use of AI systems for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:

Or. en

Justification

Article 5 is meant to protect individuals and society against intrusive forms of AI that may affect human dignity. Banning the use of social scoring by the public sector but allowing it by industry or in private settings contradicts this aim. The proposed amendment brings coherence to the text and ensures that social scoring has no place in our European society.

Amendment 327
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
(d) the use of *'real-time' remote* biometric identification systems *in publicly*	(d) the *putting into service or* use of biometric *or biometrics-based*

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:*

identification systems *that allow the comprehensive or large-scale surveillance of natural persons in any context., including surveillance in the workplace.*

Or. en

Justification

The use of biometrics or biometrics-based AI systems for large-scale monitoring or surveillance of individuals, whether real-time or not, poses an unacceptable risk of intrusion into individuals' private lives that is not limited to publicly accessible spaces or the offline world. As indicated by the European Data Protection Supervisor and Board, the use of such systems presents serious transparency and proportionality problems related to processing data of an indiscriminate number of people for the identification of only a few individuals. This can have an irreversible effect on the exercise of freedoms, including of expression, of assembly, of association, and of movement. The exceptions originally carved out in points (i), (ii) and (iii), and in paragraphs 2, 3, and 4 of this article, means that the "prohibition" originally foreseen by the Commission could turn out to be meaningless in practice as the number of suspects or perpetrators of crimes will almost always be high enough to justify the use of AI systems for suspect detection. The addition of "biometrics-based" AI systems is meant to also exclude the use of AI systems that operate by processing "weak" biometric identifiers not captured by the definition of biometric data, but that can nonetheless be used for surveillance and identification of individuals (see corresponding definition proposed in Article 3).

Amendment 328
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

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

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

Or. en

Amendment 329

Eva Kaili, Ivo Hristov

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 330
Eva Kaili, Ivo Hristov

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 331
Eva Kaili, Ivo Hristov

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	*deleted*

determined by the law of that Member State.

_____

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

Or. en

Amendment 332
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
	(da) the placing on the market, putting into service, or use of an AI system for the specific technical processing of brain or brain-generated data in order to access, infer, influence, or manipulate a person's thoughts, emotions, memories, intentions, beliefs, or other mental states against that person's will or in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. en

Justification

The rapid development of AI-powered brain-computer interfaces that can access certain components of mental information requires a dedicated provision against their potential abuse or misuse. The wording ensures that the use of neurotechnology in healthcare or clinical settings (e.g. to treat unconscious patients) would not be prohibited.

Amendment 333
Elena Kountoura

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

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

Or. en

Amendment 334
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
	(db) the putting into service or use of AI systems that allow the categorisation of individuals on the basis of their biometric, biometrics-based data, or biometric inferences into clusters according to ethnicity, gender, political or sexual orientation, or any other grounds that may lead to discrimination prohibited under Article 21 of the Charter of Fundamental Rights of the European Union;

Or. en

Justification

Allowing the use of AI systems for biometric categorisation would directly contravene the non-discrimination and equality before the law principles under the EU Charter of Fundamental Rights.

Amendment 335
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(db) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;

Or. en

Amendment 336
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
	(dc) The putting into service or use of AI systems for making individual or group assessments of natural persons in order to assess the risk of a natural person or a group of persons for offending or reoffending, or for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons or on the assessment of personality traits, characteristics, or past criminal behaviour.

Or. en

Justification

The use of predictive policing harms the presumption of innocence and impacts human dignity by denying free will. Predictive policing programmes in the United States (e.g. in New York and Cambridge) have been phased out as they have failed to make reliable predictions and have increased discriminatory outcomes.

Amendment 337
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(dc) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

Amendment 338
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(dd) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU)2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;

Or. en

Amendment 339
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(de) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of

the natural persons applying for a status;

Or. en

Amendment 340
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(df) 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 behaviour of persons in such relationships;

Or. en

Amendment 341
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:	*deleted*
(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;	
(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the	

seriousness, probability and scale of those consequences.

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

Or. en

Amendment 342
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;	*deleted*

Or. en

Amendment 343
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.	*deleted*

Amendment 344
Francesca Donato

Proposal for a regulation
Article 5 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, *in particular the* seriousness, probability *and* scale of those consequences.	(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, *irrespective of the level of* seriousness, probability *or* scale of those consequences.

Or. it

Amendment 345
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 2 – subparagraph 1

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

Or. en

Amendment 346
Eva Kaili, Ivo Hristov

Proposal for a regulation

Article 5 – paragraph 3

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

Or. en

Amendment 347
Francesca Donato

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. As regards paragraphs 1, point (d)	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.*

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.

Or. it

Amendment 348
Eva Kaili, Ivo Hristov

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 349

Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 4

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

Or. en

Amendment 350
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 5 – paragraph 4 a (new)

Text proposed by the Commission	Amendment
	4a. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of prohibited practices listed in paragraph 1 of this Article, in order to update that list on the basis of a similar threat to fundamental human rights and values.

Or. en

Given the fast pace at which AI technology is developed, there must be in-built flexibility in the AI Act to update the list of prohibited AI practices, just as there are provisions for the Commission to adopt delegated acts to amend the lists of AI techniques and approaches (Annex I), AI systems covered by safety legislation (Annex II) and high-risk AI systems (Annex III). The list of prohibited AI practices in Art 5 could be moved into a corresponding annex (Annex Ia).

Amendment 351
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

Proposal for a regulation
Article 6 – paragraph -1 (new)

Text proposed by the Commission	*Amendment*
	-1. The AI system shall be considered high-risk where it meets the following two cumulative criteria: □
	(a) the AI system is used or applied in a sector where, given the characteristics of the activities typically undertaken, significant risks of harm to the health and safety or a risk of adverse impact on fundamental rights of users, as outlined in Article 7(2) can be expected to occur.
	(b) the AI system application in the sector in question is used in such a manner that significant risks of harm to the health and safety or a risk of adverse impact on fundamental rights of users, as outlined in Article 7(2) are likely to arise.

Or. en

Amendment 352
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.   *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 353
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.	2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk. *In the event of uncertainty regarding the classification of the AI system, the supplier must deem the AI system to be high-risk if its use or application poses a risk of physical or non-physical harm to health and safety or a risk of an adverse impact to the fundamental rights of natural persons, groups of individuals or society as a whole, as set out in Article 7(2).*

Or. it

Amendment 354
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 355
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

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

Amendment

2.   In addition to the high-risk AI systems referred to in paragraph 1 *of this Article*, AI systems referred to in Annex III shall also be considered high-risk. *In case there is uncertainty over the AI system's classification, the provider shall deem the AI system high-risk if its use or application poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights of individuals affected by these technologies.*

Or. en

Amendment 356
Elena Kountoura

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.	2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk. ***The provider shall apply a precautionary principle and, in case of uncertainty over the AI system's classification, shall consider the AI system high-risk.***

Or. en

Amendment 357
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.	2. In addition to the high-risk AI systems referred to in paragraph 1***, and in accordance with paragraph -1 of this Article***, AI systems referred to in Annex III shall also be considered high-risk.

Or. en

Amendment 358
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*

	2a. AI systems referred to in Annex III shall be considered high-risk.

Or. en

Amendment 359
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where *both of* the following conditions are fulfilled:	1. The Commission is empowered to adopt delegated acts in accordance with Article 73*, following an adequate consultation with all relevant stakeholders, including, the European Artificial Intelligence Board, the EU Agency for Fundamental Rights, and the European Data Protection Supervisor,* to update the list in Annex III*,* by adding high-risk AI systems where the following conditions are fulfilled:

Or. en

Amendment 360
Elena Kountoura

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

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

Or. en

Amendment 361
Elena Kountoura

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

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

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.

economic harm, negative societal impacts or harm to the *environment,* health and safety, or a risk of adverse impact on fundamental rights*, democracy and the rule of law*, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

Or. en

Amendment 362
Jordi Solé
on behalf of the Greens/EFA Group

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

Or. en

Justification

AI can be an enabler of the twin Green-Digital transition but also a liability in achieving the climate goals. Flexibility is needed and being introduced.

Amendment 363
Miapetra Kumpula-Natri

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

Or. en

Amendment 364
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 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 **serious** risk of harm to the health and safety, or a **serious** risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact 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 365
Elena Kountoura

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, democracy and rule of law,* that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Or. en

Amendment 366
Jordi Solé
on behalf of the Greens/EFA Group

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, *a risk to climate or environment* 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:

Or. en

Justification

Change aligning para 2 with para 1

Amendment 367
Elena Kountoura

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*, democracy, rule of law and 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 368
Jordi Solé
on behalf of the Greens/EFA Group

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*, to climate or environment* or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

Or. en

Justification

Text alignment with para 1

Amendment 369
Elena Kountoura

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 370
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;	(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, *with no distinctions between AI systems with an advisory or decision-making purpose,* in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

Or. it

Amendment 371
Jordi Solé
on behalf of the Greens/EFA Group

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	(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;

reversible, whereby outcomes having an *adverse* impact on *the climate, the environment or negatively affecting the ability to achieve energy efficiency targets or* the health or safety of persons shall not be considered as easily reversible;

Or. en

Justification

Text aligned with para 1

Amendment 372
Francesca Donato

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

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

Or. it

Amendment 373
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	(g a) magnitude and likelihood of both the benefits and risks of the AI use for individuals, groups, the environment and the society at large,

Or. en

Amendment 374
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
(i) effective measures of redress in relation to the risks posed by an AI system, **with the exclusion of** claims for damages;	(i) effective measures of redress**, the availability of redress-by-design mechanisms and procedures** in relation to the risks posed by an AI system, **including** claims for **material and non-material** damages;

Or. en

Amendment 375
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(h a) The general capabilities and functions of the AI system regardless of its purpose.

Or. en

Amendment 376
Robert Roos

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

Text proposed by the Commission	*Amendment*
	(ha) the extent to which the AI system acts autonomously;

Or. nl

Amendment 377
Robert Roos

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

Text proposed by the Commission	*Amendment*
	(h a) the extent to which the AI system acts autonomously;

Or. en

Amendment 378
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	(h b) The potential misuse and malicious use of an AI system and the technology that underpins it.

Or. en

Amendment 379
Tsvetelina Penkova, Romana Jerković

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 the generally acknowledged state of the art and industry standards, including as reflected in relevant harmonised standards or common specifications*.

Amendment 380
Pilar del Castillo Vera

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**, *taking into account the generally acknowledged state of the art and industry standards,* comply with the requirements established in this Chapter.

Or. en

Amendment 381
Pilar del Castillo Vera

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 and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with *the relevant* requirements *depending of the type of risks posed*.

Or. en

Committee on Industry, Research and Energy

2021/0106(COD)

31.3.2022

AMENDMENTS
382 - 663

Draft opinion
Eva Maydell
(PE719.801v01-00)

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

EN

Amendment 382
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 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 383
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 run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It* shall comprise the following steps:	2. The risk management system shall comprise the following steps:

Or. en

Amendment 384
Elena Kountoura

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 run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:	2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic *review and* updating*, including when the high-risk AI system is subject to significant changes in its design or purpose*. It shall comprise the following steps:

Or. en

Amendment 385
Elena Kountoura

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; *In particular the risks that a high-risk AI system will:*
	(i) affect a person's legal rights or legal status;
	(ii) affect a person's access to credit, education, employment, healthcare, housing, insurance, or social welfare benefits or services, or the terms on which these are provided;
	(iii) undermine a person's safety;
	(iv) result in significant physical or psychological harm to a person;
	(v) restrict, infringe, or undermine the ability to realize a person's fundamental rights;
	(vi) breach of obligations under Union law intended to protect personal data;
	(vii) result in serious damage to the environment;

(viii) fail to achieve a high level of cybersecurity;

Or. en

Amendment 386
Francesca Donato

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 *or any* foreseeable risks associated with each high-risk AI system;

Or. it

Amendment 387
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 388
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
(d) adoption of *suitable* risk	(d) adoption of *effective* risk

management measures in accordance with the provisions of the following paragraphs.

management measures in accordance with the provisions of the following paragraphs.

Or. en

Amendment 389
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 9 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The risks referred to in paragraph 2 shall concern only those which may be sufficiently mitigated or eliminated through the use, development or design of the high-risk AI system, or the provision of adequate technical information.

Or. en

Amendment 390
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 391
Elena Kountoura

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. Those residual risks shall be communicated to the user *in a clear, easily understandable and intelligible way*.

Or. en

Amendment 392
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 393
Francesca Donato

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 *limited and* acceptable *by the user*, 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. it

Amendment 394
Robert Roos

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. Those residual risks shall be communicated to the user *or end-user when applicable*.

Or. en

Amendment 395

Elena Kountoura

Proposal for a regulation
Article 9 – paragraph 8

Text proposed by the Commission	*Amendment*
8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.	8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children*, the elderly, refugees or other vulnerable groups*.

Or. en

Amendment 396
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 9 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. The risk management system shall always identify significant impact on the environment through, inter alia, AI compute-related energy consumption, efficiency in data use, when compared with other, state-of-the-art AI systems or if it may result in significant environmental impacts or greenhouse gas emissions through the way AI is applied.

Or. en

Justification

The energy consumption and its consequences need to be taken into account.

Amendment 397
Jordi Solé
on behalf of the Greens/EFA Group

EN

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission	*Amendment*
	Article 9 a
	Impact of AI on energy consumption
	1. All AI systems shall be designed and developed to make use of state-of-the-art methods and best practice to reduce greenhouse gas emissions, computational complexities, increase energy efficiency and the efficiency of data of the system in productive use. This includes techniques involving the training and re-training or models. They shall be developed and established with capabilities that enable the measurement of the energy consumed and/or other environmental impact that the productive use of the systems may have.
	2. Providers of high-risk AI systems shall perform an environmental sustainability assessment, including on energy use, over its entire lifecycle.
	3. The assessment referred in paragraph 2 shall include information relating to:
	(a) energy consumption;
	(b) greenhouse gas emissions;
	(c) water and marine resources;
	(d) resource use, including rare metals, minerals and the circular economy;
	(e) pollution;
	(f) biodiversity and ecosystems.
	4. The assessment shall be structured in a standardised, machine readable and interoperable format that allows for publication and further comparability analysis.
	5. The Commission is empowered to adopt delegated acts in accordance with Article 73 to:

a) provide reliable, accurate and reproducible standards and methods for the environmental sustainability assessment, with particular focus on energy efficiency, to take into account recognised state-of-the-art measurement methods, or new methods that enable the comparison of the environmental impact of AI systems. The data must be understandable, relevant, representative, verifiable, comparable and represented in a faithful manner;

b) amend Annex IIIa where necessary to ensure that, in the light of technical progress, the environmental impact measurement is complete and comparable.

Or. en

Justification

Due to potential energy requirements of benefits for energy systems, measures to increase efficiency must be introduced by design.

Amendment 398
Miapetra Kumpula-Natri
on behalf of the S&D Group

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. ***Techniques such as unsupervised learning and reinforcement learning that do not use validation and testing data sets shall be developed on the basis of training data sets the quality criteria referred to in paragraphs 2 to 5.***

EN

Amendment 399
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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, ***assessment,*** validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 400
Jordi Solé
on behalf of the Greens/EFA Group

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. 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.

Or. en

Justification

Due to potential impact generated by large scale deployment, even low risk AI can present risks.

Amendment 401
Tsvetelina Penkova, Romana Jerković, Miapetra Kumpula-Natri

Proposal for a regulation
Article 10 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Providers of high-risk AI systems that utilise data collected and/or managed by third parties may rely on representations from those third parties with regard to quality criteria referred to in paragraph 2, points (a), (b) and (c).

Or. en

Amendment 402
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

Proposal for a regulation
Article 10 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The common practices standards for a high-risk AI system assessment shall be developed by the European Artificial Intelligence Board.

Or. en

Amendment 403
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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. *The* training, validation and testing *of* data sets *and the AI applications based on them* shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment 404
Elena Kountoura

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 *for the entire lifecycle of data processing*. Those practices shall concern in particular,

Or. en

Amendment 405
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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**, assessment**, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular *the following elements:*

Or. en

Amendment 406
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*

| (a) the relevant design choices; | (a) the relevant design choices; ***all appliances should be designed with the option to forbid the constantly open microphone/camera of apps and offer consumers a clear option for all recording features to be shut down when the corresponding app is not in use;*** |

Or. en

Amendment 407
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

| *Text proposed by the Commission* | *Amendment* |
| | ***(aa) transparency on the original purpose of data collection;*** |

Or. en

Amendment 408
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

| *Text proposed by the Commission* | *Amendment* |
| (b) data collection; | (b) data collection ***processes***; |

Or. en

Amendment 409
Elena Kountoura

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 biases*, including where data outputs are used as an input for future operations ('feedback loops') that are likely to affect health, fundamental rights and safety of persons or lead to discrimination prohibited by Union law*;

Or. en

Amendment 410
Adam Jarubas, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

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*, defined as a statistical error or a top-down introduction of assumptions harmful to an individual, that are likely to affect health and safety of persons or lead to discrimination prohibited by Union law*;

Or. en

Amendment 411
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 could affect fundamental rights or lead to discriminatory results, affecting both or either the individual right to non-discrimination and equality as a value recognised in Article 2 TEU.*

Amendment 412
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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, lead to discrimination prohibited by Union law or have some other impact on fundamental rights*;

Or. it

Amendment 413
Robert Roos

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*, in particular biases that are likely to affect health and safety of persons or lead to prohibited discrimination*;

Or. nl

Amendment 414
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
(f) examination in view of possible	(f) examination in view of possible biases *that are likely to affect the physical*

biases;   *health and safety of persons or lead to discrimination prohibited by Union law*; *;*

Or. en

Amendment 415
Nicola Beer, Klemen Grošelj, Iskra Mihaylova

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 416
Robert Roos

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 possible data gaps or shortcomings and*, where practicable,* how those gaps and shortcomings can be addressed.

Or. nl

Amendment 417
Elena Kountoura

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

Text proposed by the Commission	*Amendment*

Or. en

Amendment 418
Pilar del Castillo Vera

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. *Providers and users shall, when technically feasible and necessary to avoid harm, ensure that* training, validation and testing *datasets* shall be relevant, representative, *and establish reasonable procedures to mitigate errors and incomplete data sets, in view of the intended purpose of the high-risk AI system and the context of its use* 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 419
Miapetra Kumpula-Natri
on behalf of the S&D Group

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	3. Training, validation and testing data sets shall be *designed with the best possible efforts to ensure that they are*

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.

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

Amendment 420
Robert Roos

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 *must* be *as* relevant, representative, free of errors and complete *as possible in order to fulfil the purpose of the AI system*. *In particular,* they shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. nl

Amendment 421
Henna Virkkunen

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Training, validation and testing data	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.

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 422
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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 and complete*, taking into account the degree of variability within data sets*. 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. it

Amendment 423
Tsvetelina Penkova, Romana Jerković

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*, to the best extent possible,* 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.

Or. en

Amendment 424
Elena Kountoura

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, *and to the best extent possible* free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system 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 425
Eva Kaili, Ivo Hristov

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 *sufficiently* 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.

Or. en

Amendment 426
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Or. en

Amendment 427
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 10 – paragraph 5

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

Amendment 428
Robert Roos

Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission	*Amendment*
5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use	5. *(Does not affect English version.)*

of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

Or. nl

Amendment 429
Eva Kaili, Ivo Hristov

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

Text proposed by the Commission	*Amendment*
	6a. This Regulation shall guarantee the protection of citizens who choose to lead an "offline life" and ensure that there are always offline options and services available for them, especially when this concerns the provision of essential private and public services.

Or. en

Amendment 430
Francesca Donato

Proposal for a regulation
Article 11 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.	*deleted*

Or. it

Amendment 431
Francesca Donato

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be designed and developed with capabilities *enabling* the *automatic* recording *of* events ('logs') while the high-risk AI system is operating. Those logging capabilities shall conform to recognised standards or common specifications.	1. High-risk AI systems shall be designed and developed with capabilities *offering* the *technical possibility of automatically* recording events ('logs') while the high-risk AI system is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Or. it

Amendment 432
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 12 – paragraph 4 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The retention period must not exceed 10 years at most, unless specific regulations establish otherwise.

Or. it

Justification

This paragraph should be understood as a new paragraph 6.

Amendment 433
Francesca Donato

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. *All AI systems, including* 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.

Or. it

Amendment 434
Francesca Donato

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*, where applicable,* against which the 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;

Or. it

Amendment 435
Francesca Donato

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	(iii) any known or foreseeable circumstance, related to the use of the 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;

fundamental rights;

Or. it

Amendment 436
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
(d) the human *oversight* measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users;	(d) the human *supervision* measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users;

Or. it

Amendment 437
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 14 – title

Text proposed by the Commission	*Amendment*
Human *oversight*	Human *supervision*

Or. it

Amendment 438
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*

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

1.   High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use. *Human supervision should be proportionate to the task carried out by the system and should not compromise its efficiency or effectiveness.*

Or. it

Amendment 439
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the *period in which* the AI system *is in use*.	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the *whole lifecycle of* the AI system*. AI systems shall not be used to substitute, but rather to complement human decision-making*. *All AI systems shall be explainable by design.*

Or. en

Amendment 440
Francesca Donato

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine

EN

interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

interface tools, that they can *always* be effectively overseen by natural persons during the period in which the AI system is in use.

Or. it

Amendment 441
Eva Kaili, Ivo Hristov

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 *can affect the wellbeing, health or physical integrity of children and minors, or* persist notwithstanding the application of other requirements set out in this Chapter. *Special attention shall be paid on AI systems used for the development or as components of children toys.*

Or. en

Amendment 442
Francesca Donato

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	2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when *an* AI system*, especially a high-risk system,* is used in accordance

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.

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. it

Amendment 443
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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 *supervision* shall aim at *protecting* safety *and* fundamental *human* rights*, preventing or minimising the risks* 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. it

Amendment 444
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 14 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. Human *oversight* shall be ensured through either one or all of the following measures:	3. Human *supervision* shall be ensured through either one or all of the following measures:

Or. it

EN

Amendment 445
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 446
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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 *supervision* is assigned to do the following, as appropriate to the circumstances:

Or. it

Amendment 447

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 448
Miapetra Kumpula-Natri
on behalf of the S&D Group

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) *sufficiently* 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 449
Francesca Donato

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

Text proposed by the Commission	*Amendment*
(b) remain aware of the possible	(b) remain *vigilant and* aware of the

EN

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

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

Or. it

Amendment 450
Henna Virkkunen

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

Text proposed by the Commission

(d)   be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Amendment

(d)   be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system *unless 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 451
Francesca Donato

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

Text proposed by the Commission

(d)   be able to decide, in *any particular situation*, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Amendment

(d)   be able to decide, in *all cases*, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Or. it

Amendment 452
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 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 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 453
Robert Roos

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) interrupt the *AI* system through a "stop" button or a similar procedure.

Or. nl

Amendment 454
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be	1. High-risk AI systems shall be

designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle. *Compliance with these requirements shall include implementation of state-of-the-art measures, according to the specific market segment or scope of application.*

Or. it

Amendment 455
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be designed and developed in such a way that they achieve**,** in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, ***and perform consistently in those respects*** throughout their lifecycle.	1. High-risk AI systems shall be designed and developed in such a way that they achieve ***security by design and by default*** in the light of their intended purpose, ***thus reaching*** an appropriate level of accuracy, robustness**,** *safety* and cybersecurity, throughout their lifecycle.

Or. en

Justification

Security by design and by default is a principle based approach for market access that is becoming the standard for various services and products, therefore must also be included for AI

Amendment 456
Francesca Donato

Proposal for a regulation
Article 15 – paragraph 1

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

Or. it

Amendment 457
Elena Kountoura

Proposal for a regulation
Article 15 – paragraph 1

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

Or. en

Amendment 458
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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

Text proposed by the Commission	*Amendment*
	1a. The definition of "appropriate level" in terms of cybersecurity shall be provided by the European Union Agency for Cybersecurity (ENISA) in line with Article 42(2).

Or. en

Amendment 459
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.	2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use. *European Artificial Intelligence Board shall define a common methodology for the definition and communication of these metrics also referred to in Article 9(7).*

Or. en

Amendment 460
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.	2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be *assessed by an independent entity and* declared in the accompanying instructions of use. *The language used shall be clear, free of misunderstandings or misleading statements.*

Or. en

Justification

Commercial claims are too often on the fine line set by rules on misleading advertisement, therefore independent assessment and clarity need to be introduced.

Amendment 461
Tsvetelina Penkova, Romana Jerković

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 of* High-risk AI systems shall *take appropriate technical and organizational measures to ensure that high-risk AI systems are* resilient as regards *to* errors, *fault* or inconsistencies that may occur within the system or the environment in which the system operates, *consistent with industry best practices*.

Or. en

Amendment 462
Francesca Donato

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. *All* 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.

Or. it

Amendment 463
Nicola Beer, Klemen Grošelj, Iskra Mihaylova

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

Text proposed by the Commission	*Amendment*

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

The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans *by the provider, or where appropriate the users of the product with input from the user, where considered necessary*.

Or. en

Amendment 464
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs due to outputs used as an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

Amendment

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs due to outputs used as an input for future operations ('feedback loops') *and malicious manipulation of inputs used in learning during operation* are duly addressed with appropriate mitigation measures.

Or. en

Amendment 465
Francesca Donato

Proposal for a regulation
Article 15 – paragraph 4 – introductory part

Text proposed by the Commission

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

Amendment

4. *All AI systems, especially* high-risk systems*,* shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities.

Amendment 466
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 15 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. High-risk AI systems shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities.	4. High-risk AI systems shall be resilient as regards *to* attempts by unauthorised third parties to alter their use*, behaviour, outputs* or performance by exploiting the system vulnerabilities.

Or. en

Amendment 467
Francesca Donato

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

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

Or. it

Amendment 468
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The technical solutions to address AI	The technical solutions to address AI

EN

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

specific vulnerabilities shall include, where appropriate, measures to prevent*, detect, respond to, resolve* and control for attacks trying to manipulate the training dataset ('data poisoning'), *or pretrained components used in training ('model poisoning') ,* inputs designed to cause the model to make a mistake('adversarial examples' *or 'model evasion'*), *confidentiality attacks* or model flaws.

Or. en

Amendment 469
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.	The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws *which could lead to harmful decision-making*.

Or. en

Amendment 470
Francesca Donato

Proposal for a regulation
Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the	The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for *every possible attack, including*

training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Or. it

Amendment 471
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 15 – paragraph 4 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	High risk AI shall be accompanied by security solutions and patches for the lifetime of the embedded product, or in case of the absence of dependence on a specific product, for a time that needs to be stated by the manufacturer and cannot be less then 10 years.

Or. en

Justification

Security needs to be ensured for long term AI use

Amendment 472
Francesca Donato

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Providers of **high-risk** AI systems shall:	Providers of AI systems**, and high-risk systems in particular,** shall:

Or. it

Amendment 473
Francesca Donato

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

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

Or. it

Amendment 474
Francesca Donato

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

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

Or. it

Amendment 475
Francesca Donato

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

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

Or. it

Amendment 476
Pilar del Castillo Vera

Proposal for a regulation
Article 17 – paragraph 1 – introductory part

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

Or. en

Amendment 477
Pilar del Castillo Vera

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.	2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's **and user's** organisation.

Or. en

Amendment 478
Francesca Donato

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Providers of **high-risk** AI systems	1. Providers of AI systems shall keep

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

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

Or. it

Amendment 479
Robert Roos

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. *The logs shall be kept for a period that is appropriate* in the light of the intended purpose of high-risk AI system *and applicable legal obligations under Union or national law*.	1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. *They shall keep them for at least six months, unless otherwise stipulated in the applicable Union or national law, or if strictly necessary* in the light of the intended purpose of high-risk AI system.

Or. nl

Amendment 480
Francesca Donato

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated

by their *high-risk* AI systems as part of the documentation under Article 74 of that Directive.

by their AI systems as part of the documentation under Article 74 of that Directive.

Or. it

Amendment 481
Francesca Donato

Proposal for a regulation
Article 21 – paragraph 1

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

Or. it

Amendment 482
Francesca Donato

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
Where the *high-risk* AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the	Where the AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the

notified body that issued a certificate for the **high-risk** AI system, in particular of the non-compliance and of any corrective actions taken.

notified body that issued a certificate for the AI system, in particular of the non-compliance and of any corrective actions taken.

Or. it

Amendment 483
Robert Roos

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.	Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.
	National authorities shall exercise restraint in the requesting of information that could be regarded as a trade secret. Should they nevertheless request such information, they shall treat it as strictly confidential.

Or. nl

Amendment 484
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, *in an* official *Union language* determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.	Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, *one or several* official *languages* determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Or. en

Justification

Increasing transparency and access to information.

Amendment 485
Francesca Donato

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the *high-risk* AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State	*All* providers of AI systems*, especially high-risk systems,* shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State

concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the *high-risk* AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Or. it

Amendment 486
Francesca Donato

Proposal for a regulation
Article 26 – paragraph 2

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

Or. it

Amendment 487
Francesca Donato

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the *high-risk* AI system or,	3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the AI system or, where that

where that is not possible, on its packaging or its accompanying documentation, as applicable.

is not possible, on its packaging or its accompanying documentation, as applicable.

Or. it

Amendment 488
Francesca Donato

Proposal for a regulation
Article 26 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Importers shall ensure that, while *a high-risk* AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.	4. Importers shall ensure that, while *an* AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.

Or. it

Amendment 489
Francesca Donato

Proposal for a regulation
Article 26 – paragraph 5

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

cooperate with those authorities on any action national competent authority takes in relation to that system.

cooperate with those authorities on any action national competent authority takes in relation to that system.

Or. it

Amendment 490
Francesca Donato

Proposal for a regulation
Article 27 – paragraph 2

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

Or. it

Amendment 491
Francesca Donato

Proposal for a regulation
Article 27 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Distributors shall ensure that, while *a high-risk* AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of this Title.	3. Distributors shall ensure that, while *an* AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of this Title.

Amendment 492
Francesca Donato

Proposal for a regulation
Article 27 – paragraph 4

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

Or. it

Amendment 493
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
	(ca) they place on the market or put into service, in one of the uses or sectors listed by Annex II and Annex III, an AI system not originally or specifically

developed for those uses or sectors, or make a substantial modification to, or train an AI system so as to qualify it for one of the uses or sectors listed by Annex II and Annex III, whereas the AI system was not originally or specifically developed for those uses or sectors.

Or. en

Amendment 494
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article 28 a
	Obligations for providers of general-purpose AI systems
	1. Any legal entity that 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 for an intended high-risk purpose, that makes it subject to this Regulation, shall be considered the provider of the AI system in accordance with this Regulation.
	2. Providers of general-purpose AI systems used shall be obliged to ensure, through technical means, the transparency and the auditability required for downstream providers to comply with the obligations outlined in the Chapter 2 and Chapter 3 of the title III of this Regulation. In addition, the provider of general-purpose AI system shall provide additional information on the relevant limitations of the general purpose AI systems, as well as potential risks to fundamental rights, environment or the society at large.

3. This information shall be made available to developers utilising such general purpose AI systems as part of the products delivered to the markets.

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

Or. en

Amendment 495
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 29 – paragraph 2

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

Or. it

Amendment 496
Tsvetelina Penkova, Romana Jerković

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29 a
	Jurisdiction and territoriality
	Providers as defined in point 2 of Article 3 and within the meaning of Article 28, paragraph 1, shall be deemed to be under the jurisdiction of the Member State in which they have their main establishment

in the Union.

Or. en

Amendment 497
Elena Kountoura

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29 a
	Obligation on users to define affected persons
	Before putting into use a high-risk AI system as defined in Article 6(2), the user shall define categories of natural persons and groups likely to be affected by the use of the system.

Or. en

Amendment 498
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29 a
	Obligations on user to define affected persons
	1. Before implementing a high-risk AI system as defined in Article 6(2), the user shall describe persons or groups of natural persons likely to be affected by the use of the system.

Or. en

Amendment 499
Elena Kountoura

Proposal for a regulation
Article 29 b (new)

Text proposed by the Commission	*Amendment*

Article 29 b

Fundamental rights impact assessments for high-risk AI systems

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

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

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

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

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

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

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

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

h. clear steps as to how the harms identified will be mitigated, and how

effective this mitigation is likely to be.

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

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

4. In the course of the impact assessment, the user shall notify relevant national authorities and all relevant stakeholders with a view to receiving input into the impact assessment.

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

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

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

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

Or. en

Amendment 500
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 29 b (new)

Text proposed by the Commission	*Amendment*
	Article 29 b
	Fundamental rights impact assessment for high risk AI system
	1. Users of high-risk AI systems defined in Article 6(2) shall assess the systems' impact of the use prior to putting the system into work.
	2. This assessment shall include, but is not limited to, the following:
	a) a clear outline of the intended purpose for which the system will be used´;
	b) a clear outline of the intended geographic and temporal scope of the system's use
	c) the reasonably foreseeable impacts on fundamental rights of the persons affected by the high-risk AI system,
	d) the reasonably foreseeable risk of harm likely to impact marginalized persons or those groups at risk of discrimination, or increase existing societal inequalities;
	e) the reasonably foreseeable impact of the use of the system on the environment,
	f) in case of identification of reasonably foreseeable harms, clear steps as to how these harms will be addressed
	3. The obligation outlined under paragraph 1 applies for each new deployment of the high-risk AI system
	4. Where, following the impact assessment process, the user decides to put the high-risk AI system into use, the user shall be required to publish the results of the

impact assessment as part of the registration of use pursuant to their obligation under Article 51(2).

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

Or. en

Amendment 501
Tsvetelina Penkova, Romana Jerković

Proposal for a regulation
Article 38 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where a competent authority of a Member State requires obtaining an EU declaration of conformity of a provider which has its main establishment in another Member State, that request shall be made through the competent authority of the Member State where the provider has its main establishment. The information shall be transmitted by the provider in an official language of the Member State where it has its main establishment. The Commission is empowered to adopt delegated acts in accordance with this paragraph to further define the modalities for issuing and handling such requests.

Or. en

Amendment 502
Francesca Donato

Proposal for a regulation
Article 40 – paragraph 1

Text proposed by the Commission	*Amendment*

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

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

Or. it

Amendment 503
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	The Commission shall ensure that the process of developing harmonised standards includes an assessment of risks to fundamental rights, environment and society at large.

Or. en

Amendment 504
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	The Commission shall ensure that the process developing harmonised standards on artificial intelligence systems is open to stakeholders listed in the Article 5 of Regulation (EU) No 1025/2012. The Commission shall direct funds to stakeholders listed in Annex III of that Regulation in line with the Article 17 of

that regulation to facilitate effective participation of the stakeholders with particular emphasis on the relevant stakeholders for the paragraph 2.

Or. en

Amendment 505
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	The Commission shall review the harmonized standards before they are published in the Official Journal and prepare a report outlining their adequacy with paragraph 2 of this Article.

Or. en

Amendment 506
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 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	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 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

Article 74(2).

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 507
Miapetra Kumpula-Natri
on behalf of the S&D Group

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**, where relevant,** the views of relevant **stakeholders, such as SME's and start-ups, civil society and social partners** or expert groups established under relevant sectorial Union law.

Or. en

Amendment 508
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 *paragraph 1*, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union	2. The Commission, when preparing the common specifications referred to in *paragraph1*, shall gather the views of *the developers and providers of High-risk AI systems and* relevant bodies or expert

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 509
Francesca Donato

Proposal for a regulation
Article 41 – paragraph 3

Text proposed by the Commission	*Amendment*
3. **High-risk** AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.	3. AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.

Or. it

Amendment 510
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

Proposal for a regulation
Article 42 – paragraph 1

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

Article 10(4).

Or. en

Amendment 511
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 42 – paragraph 1

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

Or. en

Amendment 512
Elena Kountoura

Proposal for a regulation
Article 43 – paragraph 1 – introductory part

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

Or. en

Amendment 513
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
(a) the conformity assessment procedure based on internal control referred to in Annex VI;	*deleted*

Or. en

Amendment 514
Elena Kountoura

Proposal for a regulation
Article 43 – paragraph 2

Text proposed by the Commission	*Amendment*
2. *For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body.* For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.	2. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.

Or. en

Amendment 515
Elena Kountoura

Proposal for a regulation

Article 43 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.	*deleted*

Or. en

Amendment 516
Elena Kountoura

Proposal for a regulation
Article 43 – paragraph 6

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

Or. en

EN

Amendment 517
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 44 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in *an* official *Union language* determined by the Member State in which the notified body is established or *in an* official *Union language* otherwise acceptable to the notified body.	1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in *one or several* official *languages* determined by the Member State in which the notified body is established or *one or several* official *languages* otherwise acceptable to the notified body.

Or. en

Justification

Increasing transparency and access to information.

Amendment 518
Francesca Donato

Proposal for a regulation
Article 47

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

Or. it

Amendment 519
Tsvetelina Penkova, Romana Jerković, Miapetra Kumpula-Natri

Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*

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

1.   The provider shall draw up a written EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be given to the relevant national competent *authority in the Member State of main establishment of the provider, upon the competent authority's* request.

Or. en

Amendment 520
Francesca Donato

Proposal for a regulation
Article 48 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU declaration of conformity shall state that the *high-risk* AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the *high-risk* AI system is made available.	2. The EU declaration of conformity shall state that the AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the AI system is made available.

Or. it

Amendment 521
Tsvetelina Penkova, Miapetra Kumpula-Natri

Proposal for a regulation
Article 48 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be *translated* into an official *Union* language *or languages required by* the Member State*(s)* in which the high-risk AI system *is made available*.	2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be *presented* into an official language *of* the Member State in which *the provider of* the high-risk AI system *has its main establishment*.

Or. en

Amendment 522
Elena Kountoura

Proposal for a regulation
Article 51 – paragraph 1

Text proposed by the Commission	*Amendment*
Before placing on the market or putting into service *a high-risk* AI system referred to in *Article 6(2),* the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.	*1.* Before placing on the market or putting into service *an* AI system referred to in *the following paragraphs* the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60.

Or. en

Amendment 523
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Jerzy Buzek

Proposal for a regulation
Article 51 – paragraph 1

Text proposed by the Commission	*Amendment*
Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative	*1.* Before placing on the market or putting into service a high-risk AI system referred to in Article 6(2), the provider or, where applicable, the authorised representative

shall register that system in the EU database referred to in Article 60.

Or. en

Amendment 524
Elena Kountoura

Proposal for a regulation
Article 51 – paragraph 1 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) a high-risk AI system referred to in Article 6(2);

Or. en

Amendment 525
Elena Kountoura

Proposal for a regulation
Article 51 – paragraph 1 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) any AI system referred to in Article 52, paragraphs 1b and 2;

Or. en

Amendment 526
Elena Kountoura

Proposal for a regulation
Article 51 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	2. Before using an AI system referred to in the following paragraphs the user or, where applicable, the authorised representative shall register the uses of

that system in the EU database referred to in Article 60. A new registration entry must be completed by the user for each use of any of these AI systems:

a. high-risk AI systems referred to in Article 6 paragraph 2;

b. any AI system referred to in Article 52 paragraphs 1b and 2.

Or. en

Amendment 527
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

Proposal for a regulation
Article 51 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	2. A high-risk AI system designed, developed, trained, validate, tested or approved to be placed on the market or put into service, outside the EU, can be registered in the EU database referred to in Article 60 and placed on the market or put into service in EU only if it is proven that at all the stages of its design, development, training, validation, testing or approval, all the obligations required from such AI systems in EU have been met.

Or. en

Amendment 528
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 51 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*

Before using a high-risk AI system referred to in Article 6(2) the user or where applicable the authorised representative shall register the uses of that system in the EU database referred to in the Article 60. A new registration entry must be complemented by the user for each high risk use of the AI system.

Or. en

Amendment 529
Elena Kountoura

Proposal for a regulation
Article 51 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	3. Before using an AI system, public authorities shall register the uses of that system in the EU database referred to in Article 60. A new registration entry must be completed by the user for each use of an AI system.

Or. en

Amendment 530
Francesca Donato

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,*	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.

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

Or. it

**Amendment 531
Elena Kountoura**

**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 *in a clear, easily understandable and intelligible way* 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 532
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	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

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.

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 533
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 *and legal* 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 *authorized* 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 534
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*

1a.   Users of a high-risk AI system, referred to in Article 6(2), shall inform natural and legal persons exposed thereto of the operation of the system.

Or. en

Amendment 535
Elena Kountoura

Proposal for a regulation
Article 52 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Users of a high-risk AI system, referred to in Article 6(2), shall inform natural persons exposed thereto of the operation of the system.

Or. en

Amendment 536
Francesca Donato

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. *This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.*	2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto.

Or. it

Amendment 537
Elena Kountoura

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. ***This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.***	2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto.

Or. en

Amendment 538
Elena Kountoura

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 image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose ***in an appropriate, clear and visible manner,*** that the content has been artificially generated or manipulated.

Or. en

Amendment 539
Patrizia Toia, Miapetra Kumpula-Natri

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 image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose *in an appropriate clear and visible manner* that the content has been artificially generated or manipulated.

Or. en

Amendment 540
Francesca Donato

Proposal for a regulation
Article 52 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.	*deleted*

Or. it

Amendment 541
Elena Kountoura

Proposal for a regulation
Article 52 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*

However, the first subparagraph shall not apply where the *use is authorised by law to detect, prevent, investigate and prosecute criminal offences* or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.

However, the first subparagraph shall not apply where the *content forms part of an evidently artistic, creative or fictional cinematographic and analogous work,* or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.

Or. en

Amendment 542
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Text proposed by the Commission	*Amendment*
	3a. Users of AI systems referred to in paragraphs 1, 1a, 1b, 2, and 3 shall, when a decision made by or with the assistance of these AI systems produces legal effects concerning a natural person or otherwise significantly affects them, provide the affected person, following their request, with an explanation of the decision. The explanation shall be provided in a clear, and comprehensible manner and shall include meaningful, relevant information on the reasons for the decision, at a minimum:
	(a) the role of AI system in the decision-making process
	(b) the logic involved, the main parameters of decision-making and the relative weights.
	(c) the indication of specific personal data of the affected person, or other information, that had significant impact on the outcome,

(d) the category or group into which the affected person has been classified,

(e) whether there was a meaningful human oversight in the decision-making process.

(f) the information about the rights to remedy under this Regulation, including the right to lodge a complaint with the national supervisory authority as per Article 52c of this Regulation.

Or. en

Amendment 543
Elena Kountoura

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

Text proposed by the Commission	*Amendment*
	3a. Providers of any AI system shall 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 544
Elena Kountoura

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. *5.* Paragraphs 1, 2*, 3 and 3a* shall not affect the requirements and obligations set out in Title III of this Regulation.

Amendment 545
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 546
Robert Roos

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.
	3. Paragraph 2 shall apply, mutatis mutandis, to any person who integrates a general purpose AI-system made available on the market, with or without modifying it, into an AI-system whose intended purpose makes it subject to the provisions of this Regulation.
	4. The provisions of this Article shall apply irrespective of whether the general purpose AI-system is open source software or not.

Or. en

Amendment 547
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 a (new)

Text proposed by the Commission	*Amendment*
	Article 52 a
	Right not to be subject to non-compliant AI systems
	Natural and legal persons shall have the right not to be subjected to AI systems, which are posing an unacceptable risk pursuant to Article 5, or do not comply with the requirements of this Regulation.

Or. en

Amendment 548
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 b (new)

Text proposed by the Commission	*Amendment*
	Article 52 b
	Right to information about the use and functioning of AI systems
	1. Natural and legal persons shall have the right to be informed that they are being subjected to a high-risk AI system as defined in Article 6, or other AI systems as defined in Article 52.
	2. Natural and legal persons shall have the right to be informed, upon request, about the reasons for a decision, producing legal effects or significantly affecting them, taken with the assistance of AI system as specified in Article 52 (3a) of this Regulation.
	3. The information outlined in paragraphs 1 and 2 shall be provided in a clear and comprehensible manner.

Or. en

EN

Amendment 549
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 c (new)

Text proposed by the Commission	*Amendment*
	Article 52 c
	Right to lodge a complaint with a national supervisory authority
	1. Natural and legal persons who consider that their rights under this Regulation have been infringed shall have the right to lodge a complaint against the provider or user with a national supervisory authority in the Member State of his or her residence, place of work, or place of the alleged infringement.
	2. National supervisory authorities shall have the duty to investigate, in conjunction with relevant market surveillance authority if applicable, the alleged infringement and inform the complainant, within a period of 6 months, of the outcome of the complaint, including the possibility of a judicial remedy pursuant to Article 52e.

Or. en

Amendment 550
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 d (new)

Text proposed by the Commission	*Amendment*
	Article 52 d
	Representation of natural persons and the right for public interest organisations to

lodge a complaint with national supervisory authority

1. Natural and legal persons who consider that their rights under this Regulation have been infringed shall have the right to ask a public interest organisation to lodge a complaint on their behalf with a national competent authority and to exercise on their behalf their rights as referred to in Articles 52c and 52e.

2. A public interest organization is a not-for-profit body, organization or association which has been properly established in accordance with the law of a Member State, has statutory objectives which are in the public interest.

3. Public interest organisations shall have the right to lodge complaints with national competent authorities, independently of the mandate of the natural or legal person, if they consider that an AI system has been placed on the market, put into service, or used in a way that infringes this Regulation, or is otherwise in violation of fundamental rights or other aspects of public interest protection, pursuant to article 67.

4. National supervisory authorities have the duty to investigate, in conjunction with relevant market surveillance authority if applicable, and respond within a period of 6 months to all complaints made by public interest organizations.

Or. en

Amendment 551
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 e (new)

EN

Text proposed by the Commission	*Amendment*
	Article 52 e
	Right to an effective remedy against the national supervisory authority
	1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a national supervisory authority concerning them.
	2. Without prejudice to any other administrative or non-judicial remedy, each natural and legal person shall have the right to an effective judicial remedy where the national supervisory authority does not handle a complaint or does not inform the person within 6 months on the progress or outcome of the complaint lodged pursuant to Articles 52c and 52d.
	3. Proceedings against a national supervisory authority shall be brought before the courts of the Member State where the national supervisory authority is established.

Or. en

Amendment 552
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 52 f (new)

Text proposed by the Commission	*Amendment*
	Article 52 f
	Right to an effective remedy against a user for the infringement of rights
	1. Without prejudice to any available administrative or non-judicial remedy, any natural and legal person shall have

the right to an effective judicial remedy against a user where they consider that their rights under this Regulation have been infringed or they have been subject to an AI system in non-compliance with this Regulation.

2. Any natural and legal person who has suffered material or non-material damage due to an infringement of this Regulation shall have the right to receive compensation from the user for the damage suffered.

Or. en

Amendment 553
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 *the Commission in collaboration with* one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the *safe* development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance *of the Commission in collaboration with* 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. *The Commission shall play a complementary role, allowing those Member States with demonstrated experience with sandboxing to build on their expertise and, on the*

other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes.

Or. en

Amendment 554
Romana Jerković, Robert Hajšel, Miapetra Kumpula-Natri

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, *and in collaboration with SMEs, start-ups, enterprises and other innovators,* 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. *For Member States competent authorities or the European Data Protection Supervisor,* this shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. *SMEs, start-ups, enterprises and other innovators shall conduct live experiments for new business models in collaboration with the Member State competent authorities.*

Or. en

Amendment 555

Elena Kountoura

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 *strictly* 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 *identifying risks in particular to health, safety, and fundamental rights,* ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.

Or. en

Amendment 556
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 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	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 *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

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.

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 557
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
	1a. The controllers of personal data referred to in Article 4(7) of 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 558
Romana Jerković, Robert Hajšel, Miapetra Kumpula-Natri

Proposal for a regulation
Article 53 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national authorities are associated to the operation of the AI regulatory sandbox.	2. Member States shall ensure that to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national authorities are associated to the operation of the AI regulatory sandbox *established by one or more Member States competent authorities or the European Data Protection Supervisor*. *Start-ups, SMEs, enterprises and other innovators may request access to personal data from relevant national authorities to be used in their AI sandbox while ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox*

Or. en

Amendment 559
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 53 – paragraph 2

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

Amendment 560
Elena Kountoura

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. *Regulatory sandboxes involving activities that may impact* health*,* safety and fundamental rights*, democracy and rule of law or the environment shall be developed in accordance with redress-by-design principles. Any significant risks* identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.

Or. en

Amendment 561
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 53 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the 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	3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities *and can only be implemented in a specified area with approval of the regional or local authorities*. Any significant risks to *environment,* health and safety and fundamental rights identified during the development and

| | testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. |

mitigation takes place.

<div align="right">Or. en</div>

Justification

THe role of regional and local authorities needs to be maintained and their powers cannot be diminished without approval.

Amendment 562
Francesca Donato

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 and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation *or closure of the sandbox* and, failing that, in the suspension of the development and testing process until such mitigation takes place.

<div align="right">Or. it</div>

Amendment 563
Romana Jerković, Robert Hajšel, Miapetra Kumpula-Natri

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	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.

powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of *AI* systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.

Or. en

Amendment 564
Romana Jerković, Robert Hajšel, Miapetra Kumpula-Natri

Proposal for a regulation
Article 53 – paragraph 5

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

Or. en

Amendment 565
Miapetra Kumpula-Natri
on behalf of the S&D Group

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

Or. en

Amendment 566
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 53 – paragraph 5

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

EN

Justification

Underlining the importance of energy use

Amendment 567
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 568
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 53 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Commission shall establish an EU AI Regulatory Sandboxing Programme whose modalities referred to in Article 53(6) shall cover the elements set out in Annex IXa. The Commission shall proactively coordinate with national

and local authorities, where relevant.

Or. en

Amendment 569
Robert Roos

Proposal for a regulation
Article 55 – title

Text proposed by the Commission	*Amendment*
Measures for *small-scale providers* and users	Measures for *SMEs* and users

Or. nl

Amendment 570
Francesca Donato

Proposal for a regulation
Article 55 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Member States *shall* undertake the following actions:	1. Member States *may* undertake the following actions:

Or. it

Amendment 571
Romana Jerković, Robert Hajšel, Miapetra Kumpula-Natri

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 *SME* providers*, including* start-ups with priority access to the AI regulatory sandboxes *established by one or more Member States competent authorities or the European Data*

Protection Supervisor to the extent that they fulfil the eligibility conditions;

Or. en

Amendment 572
Elena Kountoura

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 start-ups *established in the EU* with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

Or. en

Amendment 573
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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 *SME* providers*, including* start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

Or. en

Amendment 574
Robert Roos

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 **SMEs** and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

Or. nl

Amendment 575
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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 *and enhanced digital skills development* activities about the application of this Regulation tailored to the needs of *SME* providers*, including start-ups* and users;

Or. en

Amendment 576
Robert Roos

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 *SMEs* and users;

Or. nl

Amendment 577
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

EN

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 *SME* providers*, including start-ups,* and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation.

Or. en

Amendment 578
Robert Roos

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 *SMEs* and user and other innovators to provide guidance and respond to queries about the implementation of this Regulation.

Or. nl

Amendment 579
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

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

Text proposed by the Commission	*Amendment*
	1a. 'Regulatory sandbox' means a facility established by the Commission in collaboration with one or more Member States competent authorities or the European Data Protection Supervisor that provides an appropriate controlled and

flexible environment that facilitates the safe development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan.

Or. en

Amendment 580
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

Proposal for a regulation
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The specific interests and needs of the *small-scale* providers shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.	2. The specific interests and needs of the *SME* providers*, including start-ups,* shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their *development stage,* size and market size.

Or. en

Amendment 581
Robert Roos

Proposal for a regulation
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The specific interests and needs of the *small-scale providers* shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.	2. The specific interests and needs of the *SMEs* shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.

Or. nl

Amendment 582
Nicola Beer, Klemen Grošelj, Iskra Mihaylova, Martina Dlabajová

Proposal for a regulation
Article 55 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall regularly assess the certification and compliance costs for SMEs, including start-ups, through consultations with the SME providers, start-ups and users.

Or. en

Amendment 583
Josianne Cutajar, Miapetra Kumpula-Natri

Proposal for a regulation
Article 55 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where appropriate, Member States shall find synergies and cooperate via relevant instruments funded by EU programmes, such as the European Digital Innovation Hubs.

Or. en

Amendment 584
Elena Kountoura

Proposal for a regulation
Article 55 a (new)

Text proposed by the Commission	*Amendment*
	Article 55 a
	Right not to be subject to non-compliant AI systems
	1. Natural persons shall have the right not

to be subject to AI systems that:

(a) pose an unacceptable risk pursuant to Article 5, or

(b) otherwise do not comply with the requirements of this Regulation.

Or. en

Amendment 585
Elena Kountoura

Proposal for a regulation
Article 55 b (new)

Text proposed by the Commission	*Amendment*
	Article 55 b
	Right to information about the use and functioning of AI systems
	1. Natural persons shall have the right to be informed that they have been exposed to high-risk AI systems as defined in Article 6, and other AI systems as defined in Article 52.
	2. Natural persons shall have the right to be provided upon request, with an explanation for decisions producing legal effects or otherwise significantly affecting them or outcomes related to them taken by or with the assistance of systems within the scope of this Regulation, pursuant to Article 52 paragraph (3b).
	3. The information outlined in paragraphs 1 and 2 shall be provided in a clear, easily understandable and intelligible way, in a manner that is accessible for persons with disabilities.

Or. en

Amendment 586
Elena Kountoura

Proposal for a regulation
Article 55 c (new)

Text proposed by the Commission	*Amendment*
	Article 55 c
	Right to lodge a complaint with a national supervisory authority
	1. Natural persons affected by the operation of AI systems within the scope of this Regulation, who consider that their rights under this Regulation have been infringed shall have the right to lodge a complaint with a national supervisory authority in the Member State of their habitual residence, place of work, or place of the alleged infringement.
	2. National supervisory authorities have the duty to investigate, in conjunction with relevant market surveillance authority if applicable, the alleged infringement and inform the complainant, within a period of 3 months, of the outcome of the complaint, including the possibility of a judicial remedy pursuant to Article 55e.

Or. en

Amendment 587
Elena Kountoura

Proposal for a regulation
Article 55 d (new)

Text proposed by the Commission	*Amendment*
	Article 55 d
	Representation of natural persons and the right for public interest organisations to lodge a complaint with national supervisory authority
	1. Natural persons who consider that their rights under this Regulation have been

infringed shall have the right to mandate a public interest organisation to lodge a complaint on their behalf with a national competent authority and to exercise on their behalf their rights as, referred to in Articles 55c and 55e.

2. Public interest organisations shall have the right to lodge complaints with national competent authorities, independently of the mandate of the natural person, if they consider that an AI system has been placed on the market, put into service, or used in a way that infringes this Regulation, or is otherwise in violation of fundamental rights or other aspects of public interest protection, pursuant to article 67.

Or. en

Amendment 588
Elena Kountoura

Proposal for a regulation
Article 55 e (new)

Text proposed by the Commission	*Amendment*
	Article 55 e
	Right to an effective remedy against the national supervisory authority
	1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a national supervisory authority concerning them.
	2. Without prejudice to any other administrative or non-judicial remedy, each natural person shall have the right to an effective judicial remedy where the national supervisory authority does not handle a complaint or does not inform the person within three months on the

progress or outcome of the complaint lodged pursuant to Articles 55c and 55d.

3. Proceedings against a national supervisory authority shall be brought before the courts of the Member State where the national supervisory authority is established.

Or. en

Amendment 589
Elena Kountoura

Proposal for a regulation
Article 55 f (new)

Text proposed by the Commission	*Amendment*
	Article 55 f
	Right to an effective remedy against a user for the infringement of rights
	1. Without prejudice to any available administrative or non-judicial remedy, any natural person shall have the right to an effective judicial remedy against a user where they consider that their rights under this Regulation have been infringed or has been subject to an AI system otherwise in non-compliance with this Regulation.
	2. Any person who has suffered material or non-material damage as a result of an infringement of this Regulation shall have the right to receive compensation from the user for the damage suffered.

Or. en

Amendment 590
Lina Gálvez Muñoz, Miapetra Kumpula-Natri, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Article 56 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) *contribute to the* effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;	(a) *promote and support* effective cooperation of the national supervisory authorities and the Commission with regard to matters covered by this Regulation;

Or. en

Amendment 591
Lina Gálvez Muñoz, Ibán García Del Blanco, Carlos Zorrinho, Robert Hajšel, Romana Jerković, Adriana Maldonado López, Josianne Cutajar

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) assist developers, deployers and users of AI systems to meet the requirements of this Regulation, including those set out in present and future Union legislation, in particular SMEs and start-ups.

Or. en

Amendment 592
Robert Roos

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) consider how the Union could better develop synergies, for example through Horizon Europe and EuroHPC, in order to promote the take-up of AI.

Or. nl

Amendment 593
Elena Kountoura

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) *(d) launch an evaluation procedure for an AI system.*

Or. en

Amendment 594
Elena Kountoura

Proposal for a regulation
Article 56 – paragraph 2 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) *assist providers and users of AI systems, in particular SMEs and start-ups to meet the requirements of this Regulation.*

Or. en

Amendment 595
Eva Kaili, Ivo Hristov

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	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. *The European Union Agency for Fundamental Rights will have the status of observer in the Board.* Other national

are of relevance for them.

authorities*, as well as representatives of small and medium-sized enterprises and startups,* may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 596
Elena Kountoura

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, and the European Data Protection Supervisor*, the EU Agency for Fundamental Rights, ENISA and EIGE*. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 597
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

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

Text proposed by the Commission	*Amendment*
	3a. The Board shall establish a AI Advisory Council (Advisory Council). The Advisory Council shall be composed of relevant representatives from industry, research, academia, civil society, standardisation organisations, relevant common European data spaces and other

relevant stakeholders or third parties appointed by the Board, representing all Member States to maintain geographical balance. The Advisory Council shall support the work of the Board by providing advice relating to the tasks of the Board. The Advisory Council shall nominate a relevant representative, depending on the configuration in which the Board meets, to attend meetings of the Board and to participate in its work. The composition of the Advisory Council and its recommendations to the Board shall be made public.

Or. en

Amendment 598
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 57 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Board *may* invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.	4. The Board *shall* invite external experts and observers*, including providers with appropriate skills and proven experience in supporting Member State authorities in the preparation and management of experimentation and test facilities,* to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Or. it

Justification

Some providers have unique experience in collaborating with governments and national authorities in the creation of structures for IA experimentation and testing, and could offer relevant skills to strengthen national AI ecosystems, including support for smaller actors such

as SMEs in the experimentation and validation processes. Their regular participation in the Board could therefore provide a valuable contribution to future strategic activities and AI roadmaps.

Amendment 599
Elena Kountoura

Proposal for a regulation
Article 57 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Board *may invite* external experts and observers *to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent*. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and *advisory groups*.	4. The Board *shall be reinforced on a technical level by the creation of a specialised body of* external experts and observers. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and *the specialised body*. *The composition of the specialised body shall ensure fair representation of consumer organisations, social partners, civil society organisations and academics specialised in AI. Its meetings and their minutes shall be published online.*

Or. en

Amendment 600
Miapetra Kumpula-Natri
on behalf of the S&D Group

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	4. *When relevant,* the Board *shall* invite external experts*, in particular a standing expert on fundamental rights, and other* observers to attend its meetings and *shall* hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission *shall* facilitate exchanges

EN

advisory groups.

between the Board*,* other Union bodies, offices, agencies and advisory groups *and civil society and social partners*.

Or. en

Amendment 601
Elena Kountoura

Proposal for a regulation
Article 58 – paragraph 1 – point c – introductory part

Text proposed by the Commission	*Amendment*
(c) issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular	(c) issue *guidelines,* opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular

Or. en

Amendment 602
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) on the impacts on fundamental rights and outcomes for different groups in society, including for children and other vulnerable groups.

Or. en

Amendment 603
Elena Kountoura

Proposal for a regulation
Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) on the need for the amendment of the Annexes,

Or. en

Amendment 604
Eva Kaili, Ivo Hristov

Proposal for a regulation
Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) work towards establishing an independent and well-resourced European Regulatory Agency for Artificial Intelligence within the first two years after the entry into force of this Regulation. Among its tasks, said agency will:
	a) ensure the enforcement of this Regulation and advise and propose amendments to the European Commission when the need arises to update any of its articles, including the list of prohibited artificial intelligence practices (Article 5), the classification rules for high-risk AI systems (Article 6), or any of the annexes accompanying this Regulation;
	b) establish a risk assessment matrix for classifying algorithm types and application domains according to their potential negative impact on health, safety, the environment, or fundamental rights;
	c) collaborate with and advise other regulatory agencies and national regulators regarding Artificial Intelligence systems as they apply to the remit of those agencies (e.g. on data protection or the use of Artificial Intelligence systems used by law

enforcement or judicial agencies);

d) facilitate the effectiveness of the tort liability mechanism as means for regulating accountability of Artificial Intelligence systems by providing a contact point for citizens who are not familiar with legal procedures;

e) audit the algorithmic impact assessments of high-risk AI systems defined in Article 6(2) and Annex III, and approve or reject the proposed uses of algorithmic decision-making in highly sensitive or safety-critical application domains (e.g. private health-care);

f) investigate suspected cases of human rights violations by algorithmic decision-making systems, in both individual decision instances (e.g. singular aberrant outcomes) and statistical decision patterns (e.g. discriminatory bias);

g) produce the necessary guidelines to support the harmonised implementation of this Regulation, particularly on the establishment and operation of AI regulatory sandboxes and on the obligations of stakeholders along the AI value chain (e.g. providers, importers, and users).

Or. en

Justification

The rapid spread of AI systems across the Single Market increases the likelihood of cross-border cases that can have a significant impact on health, fundamental rights, or the environment. It is thus crucial to ensure a harmonised enforcement of this Regulation. An EU-level Regulatory Agency for AI would provide the independent oversight and expert monitoring capacity required. Its remit would go beyond that of the European AI Board, which has only an assisting role. Once constituted, this Agency could substitute the Board by incorporating its members and turning it into an autonomous organisation with enforcement and monitoring powers.

Amendment 605
Elena Kountoura

Proposal for a regulation
Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) to provide specific guidance and assistance to SMEs and start-ups regarding the compliance of the obligations set out in this Regulation;

Or. en

Amendment 606
Robert Roos

Proposal for a regulation
Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) identify and address existing bottlenecks.

Or. nl

Amendment 607
Elena Kountoura

Proposal for a regulation
Article 60 – title

Text proposed by the Commission	*Amendment*
EU database for stand-alone high-risk AI systems	EU database for stand-alone high-risk AI systems *and certain AI systems, uses thereof, and uses of AI systems by public authorities*

Or. en

Amendment 608
Elena Kountoura

Proposal for a regulation
Article 60 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article *51*.	1. The Commission shall, in collaboration with the Member States, set up and maintain a EU database containing information referred to in paragraph 2 concerning*:*
	a. high-risk AI systems referred to in Article 6(2) which are registered in accordance with Article *51(1);*
	b. *any AI system referred to in Article 52 paragraphs 1b and 2 which are registered in accordance with Article 51(1);*
	c. any uses of high-risk AI systems referred to in Article 6(2)which are registered in accordance with Article 51(2);
	d. any uses of AI systems referred to in Article 52 paragraph1b and 2 which are registered in accordance with Article 51(2);
	e. any uses of AI systems by or on behalf of public authorities registered in accordance with Article 51(3).

Or. en

Amendment 609
Elena Kountoura

Proposal for a regulation
Article 60 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The data listed in Annex VIII shall be entered into the EU database by the providers. The Commission shall provide them with technical and administrative support.	2. The data listed in Annex VIII shall be entered into the EU database by the providers *and users*. The Commission shall provide them with technical and administrative support. *The following*

information should be included in the EU database:

(a) For registrations according to paragraph 1(a) and 1(b), the data listed in Annex VIII point 1 shall be entered into the EU database by the providers.

(b) For registrations according to paragraph 1(c), 1(d) and 1(e), the data listed in Annex VIII point 2 shall be entered into the EU database by the users.

Or. en

Amendment 610
Elena Kountoura

Proposal for a regulation
Article 60 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Information contained in the EU database shall be accessible to the public.	3. Information contained in the EU database shall be accessible to the public*, comply with the accessibility requirements of Annex I to Directive 2019/882, and be user-friendly, navigable, and machine-readable, containing structured digital data based on a standardised protocol*.

Or. en

Amendment 611
Elena Kountoura

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	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.

contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider *or the user*.

Or. en

Amendment 612
Elena Kountoura

Proposal for a regulation
Article 60 – paragraph 5

Text proposed by the Commission	*Amendment*

5.   The Commission shall be the controller of the EU database. It shall also ensure to providers adequate technical and administrative support.

5.   The Commission shall be the controller of the EU database. It shall also ensure to providers *and users* adequate technical and administrative support*, in particular in relation to registrations according to paragraph 1(e)*.

Or. en

Amendment 613
Francesca Donato

Proposal for a regulation
Article 61 – paragraph 1

Text proposed by the Commission	*Amendment*

1.   Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the *high-risk* AI system.

1.   Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the AI system.

Or. it

Amendment 614
Francesca Donato

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 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. it

Amendment 615
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Article 61 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Since the sensitive nature of some high-risk AI systems, especially systems used by public authorities, agencies and institutions to prevent, investigate, detect or prosecute crimes, could result in significant restrictions on the collection and sharing of data between the end user and the provider, end users must involve the provider in the definition of aspects such as the nature of data made available for post-marketing monitoring and the degree of anonymisation of data. This should take place as early as the system design stage, in order to allow the provider to perform activities under the Regulation with a complete data set that has already been validated by the final user before the activity, and with a level of security that is proportionate to the task

carried out by the system. The end user must remain responsible for the disclosure of data contained in such groups of data.

Or. it

Justification

Since a certain number of high-risk AI systems are used by national authorities to conduct sensitive activities - such as police investigations - which renders post-marketing monitoring by providers difficult and sometimes virtually impossible, it is important that those institutional end users establish a framework for collaborating with providers and facilitating this activity as appropriate.

Amendment 616
Francesca Donato

Proposal for a regulation
Article 62 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Providers of **high-risk** AI systems placed on the Union market shall report any serious incident or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.	1. Providers of AI systems placed on the Union market shall report any serious incident or any malfunctioning of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.

Or. it

Amendment 617
Tsvetelina Penkova, Miapetra Kumpula-Natri

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	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.

surveillance authorities shall be granted access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

Or. en

Amendment 618
Tsvetelina Penkova, Miapetra Kumpula-Natri

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, the market surveillance authorities shall be granted access to the source code*, or if impossible, all related data sets used to train or place* the AI system *on the market*.

Or. en

Amendment 619
Elena Kountoura

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 of fundamental rights of persons are concerned.	1. AI systems presenting a risk shall be understood as a product presenting a risk defined in Article 3, point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety *in general, including safety in the workplace, protection of consumers, the environment,*

or to the protection of fundamental rights of persons are concerned*, including autonomy of choice, access to goods and services, unfair discrimination and economic harm, privacy and data protection, as well as societal risks*.

Or. en

Amendment 620
Elena Kountoura

Proposal for a regulation
Article 65 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).	2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the *Board and the* relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).

Or. en

Amendment 621
Elena Kountoura

Proposal for a regulation
Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.	1. Where, within three months of receipt of the notification referred to in Article 65(5), objections are raised by *the European Parliament or* a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, *or has sufficient reasons to believe that an AI system presents a risk or affects consumers in more than one Member State* the Commission shall without delay enter into consultation with the relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within 9 months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Or. en

Justification

Justification : Article 11 of Regulation (EU) No 1025/2012 on European standardisation, referred in §3 of this article 66, also allows the European Parliament to place a formal objection.

Amendment 622
Elena Kountoura

Proposal for a regulation
Article 66 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of	3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of

Regulation (EU) No 1025/2012.

Regulation (EU) No 1025/2012.*The Commission shall also have the possibility to suggest alternative measures to the Member State concerned.*

Or. en

Amendment 623
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski

Proposal for a regulation
Article 71 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of *small-scale* providers *and start-up* and their economic viability*.*	1. In compliance with the terms and conditions laid down in this Regulation, *the Commission in consultation with* Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and *in cooperation with Member States* shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the *size and the* interests of *SME* providers*, including start-ups* and their economic viability

Or. en

Amendment 624
Robert Roos

Proposal for a regulation
Article 71 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines,	1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines,

applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of **small-scale providers and start-up** and their economic viability.

applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of **SMEs** and their economic viability.

Or. nl

Amendment 625
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski

Proposal for a regulation
Article 71 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.	*deleted*

Or. en

Amendment 626
Robert Roos

Proposal for a regulation
Article 71 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.	5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

If the information supplied is incomplete, a period of two months shall be granted in which to provide the requested information.

Or. nl

Amendment 627
Francesca Donato

Proposal for a regulation
Article 72 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The following infringements shall be subject to administrative fines of up to *500 000* EUR:	2. The following infringements shall be subject to administrative fines of up to *1 000 000* EUR:

Or. it

Amendment 628
Francesca Donato

Proposal for a regulation
Article 72 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to *250 000* EUR.	3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to *500 000* EUR.

Or. it

Amendment 629
Francesca Donato

Proposal for a regulation
Article 83 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [*12* months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.	1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [*3* months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.

Or. it

Amendment 630
Tsvetelina Penkova, Miapetra Kumpula-Natri

Proposal for a regulation
Article 83 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to *significant changes* in their design or intended purpose.	2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to *substantial modifications as defined in Article 3(23)* in their design or intended purpose.

Or. en

Amendment 631
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex I – point b

Text proposed by the Commission	*Amendment*
(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;	*deleted*

Or. it

Amendment 632
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 633
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex I – point c

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

Or. it

Amendment 634
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex I – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) Approaches based on the assessment of behavioural and psychological characteristics of individuals, including activities, interests, opinions, attitudes, values and lifestyles, recognised through automatic means;

Or. it

Justification

This point should be understood as point d (new).

Amendment 635
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex III – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas.	High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas, *whose use or application poses a risk of harm to health and safety or a negative impact on the fundamental rights of natural persons, groups or society in general*.

Or. it

Amendment 636
Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) AI systems intended to be used to make inferences on the basis of biometric data, including emotion recognition systems, or biometrics-based data, including speech patterns, tone of voice, lip-reading and body language analysis, that produces legal effects or affects the rights and freedoms of natural persons.

Or. en

Amendment 637
Miapetra Kumpula-Natri
on behalf of the S&D Group

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**, digital infrastructure,** and the supply of water, gas, heating and electricity**;**

Or. en

Amendment 638
Adam Jarubas, Janusz Lewandowski, Krzysztof Hetman, Radosław Sikorski, Eva Maydell, Jerzy Buzek

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,	(a) AI systems intended to be used for recruitment or selection of natural persons, screening or filtering applications, evaluating candidates in the course of

evaluating candidates in the course of interviews or tests;

interviews or tests;

Or. en

Amendment 639
Miapetra Kumpula-Natri
on behalf of the S&D Group

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 **affecting the initiation, establishment, implementation** and termination of **an employment relationship**, **including AI systems intended to support collective legal and regulatory matters, particularly** for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships. **.**

Or. en

Amendment 640
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 641
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex III – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. *Environmental impact and energy use:*
	(a) AI systems that require a higher frequency of training and re-training of models than 60% of comparable state-of-the-art systems;
	(b) AI systems that require training or re-training of data quantities that exceed 60% of comparable state-of-the-art systems;
	(c) AI systems that require the re-training of partial data-sets involved where these exceed 20% of the data globally available to the system;
	(d) AI systems other than those which make use of techniques involving the training of models that are resource intensive than 60% of the comparable state-of-the-art systems

Or. en

Justification

Providing a methodology for assesment

Amendment 642
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission	*Amendment*

(b)   AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

deleted

Or. en

Amendment 643
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission	*Amendment*
(b) AI systems intended to be used to evaluate the *creditworthiness* of natural persons or establish their credit score, with the exception of AI systems put into service by *small scale* providers for their own use;	(b) *Following the adoption of common specifications under Article 41 of this Regulation*, AI systems intended to be used to evaluate the *credit rating* of natural persons or establish their credit score *when granting access to credit or other essential services*, with the exception of AI systems put into service by providers *on a small scale* for their own use *and AI systems based on autonomous use under human supervision of linear regression, logistic regression, decision trees and other equally transparent, explicable and interpretable techniques*;

Or. it

Amendment 644
Eva Kaili, Ivo Hristov

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b

Text proposed by the Commission	*Amendment*
(b) AI systems intended to be used to evaluate the creditworthiness of natural	(b) AI systems intended to be used to evaluate the creditworthiness of natural

EN

persons *or* establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;

persons*, establish their credit score, or predict medical human conditions and health-related outcomes*, with the exception of AI systems put into service by small scale providers for their own use;

Or. en

Amendment 645
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) AI systems intended for making individual risk assessments of natural persons in the context of access to private and public services, including determining the amounts of insurance premiums.

Or. en

Amendment 646
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) AI systems intended for or used in the context of payment and debt collection services.

Or. en

Amendment 647
Elena Kountoura

Proposal for a regulation

Annex III – paragraph 1 – point 6 – point a

Text proposed by the Commission	Amendment
(a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;	*deleted*

Or. en

Amendment 648
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission	Amendment
(b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;	*deleted*

Or. en

Amendment 649
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point e

Text proposed by the Commission	Amendment
(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal	*deleted*

behaviour of natural persons or groups;

Or. en

Amendment 650
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission	*Amendment*
(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;	*deleted*

Or. en

Amendment 651
Elena Kountoura

Proposal for a regulation
Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission	*Amendment*
(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.	*deleted*

Or. en

Amendment 652
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. **Identification and categorisation of behaviour and cognitive bias of natural persons.**

	Or. it

Justification

Point 8a should actually be understood as point 9 (new)

Amendment 653
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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) *in so far as this is without prejudice to professional secrecy, and only when the request is proportionate to the scale of the interest being preserved,* 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. it

Amendment 654
Miapetra Kumpula-Natri
on behalf of the S&D Group

EN

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

Text proposed by the Commission	*Amendment*
(d) *where relevant,* the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);	(d) the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

Or. en

Amendment 655
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

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

Text proposed by the Commission	*Amendment*
(e) assessment of the human *oversight* measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);	(e) assessment of the human *supervision* measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);

Or. it

Amendment 656
Jordi Solé
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex IV – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance*, environmental sustainability and energy efficiency*, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to *energy grids and policy, climate and environmental protection,* health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

Or. en

Justification

Changes aligning the requirements to the policy objectives introduced above

Amendment 657
Gianna Gancia, Matteo Adinolfi, Elena Lizzi, Paolo Borchia, Isabella Tovaglieri, Angelo Ciocca

Proposal for a regulation
Annex IV – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on

EN

which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human *oversight* measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human *supervision* measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

Or. it

Amendment 658
Elena Kountoura

Proposal for a regulation
Annex VIII

Text proposed by the Commission	*Amendment*
INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51	*deleted*
The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.	
1. Name, address and contact details of the provider;	
2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;	
3. Name, address and contact details of the authorised representative, where applicable;	
4. AI system trade name and any additional unambiguous reference allowing identification and traceability of	

the AI system;

5. Description of the intended purpose of the AI system;

6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);

7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;

8. A scanned copy of the certificate referred to in point 7, when applicable;

9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;

10. A copy of the EU declaration of conformity referred to in Article 48;

11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.

12. URL for additional information (optional).

Or. en

Amendment 659
Elena Kountoura

Proposal for a regulation
Annex VIII – title

Text proposed by the Commission	*Amendment*
INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51	INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS *, USES THEREOF, AND USES OF AI SYSTEMS BY PUBLIC AUTHORITIES* IN ACCORDANCE WITH ARTICLE 51

Amendment 660
Elena Kountoura

Proposal for a regulation
Annex VIII – paragraph 1

Text proposed by the Commission	*Amendment*
The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.	*1* The following information shall be provided and thereafter kept up to date *by the provider* with regard to high-risk AI systems *referred to in Article 6(2)and to any AI system referred to in Article 52 1(b) and (2)* to be registered in accordance with Article 51 *(1):*
	(a) Name, address and contact details of the provider;
	(b) Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;
	(c) Name, address and contact details of the authorised representative, where applicable;
	(d) AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;
	(e) Description of the intended purpose of the AI system;(f) Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);
	(g) Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;
	(h) A scanned copy of the certificate referred to in point 7,when applicable;
	(i) Member States in which the AI system is or has been placed on the market, put into service or made available in the

EN

Union;

(j) A copy of the EU declaration of conformity referred to in Article 48;

(k) Electronic instructions for use as listed in Article 13(3) and basic explanation of the general logic and key design as listed in Annex IV point 2(b) and of optimization choices as listed in Annex IV point (3).

(l) Assessment of the environmental impact, including but not limited to resource consumption, resulting from the design, data management and training, and underlying infrastructures of the AI system, and of the methods to reduce such impact;

(m) A description of how the system meets the relevant accessibility requirements of Annex I to Directive 2019/882.

(n) URL for additional information (optional).

Or. en

Amendment 661
Elena Kountoura

Proposal for a regulation
Annex VIII – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	2. The following information shall be provided and thereafter kept up to date by the user with regard to uses of high-risk AI systems referred to in Article 6(2) and any AI system referred to in Article 52 1(b) and (2) to be registered in accordance with Article 51(2):
	(a) Name, address and contact details of the user;
	(b) Where submission of information is carried out by another person on behalf of the user, the name, address and contact

details of that person;

(c) Name, address and contact details of the authorised representative, where applicable;

(d) URL of the entry of the AI system in the EU database by its provider, or, where unavailable, AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;

(e) Description of the intended purpose of the intended use of the AI system;

(f) Description of the context and the geographical and temporal scope of application, geographic and temporal, of the intended use of the AI system;

(g) Basic explanation of design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to categories persons or groups of persons on which the system is intended to be used; the main classification choices; and what the system is designed to optimise for and the relevance of the different parameters.

(h) For high-risk AI systems and for systems referred to in Article 52 1(b) and (2), designation of persons foreseeably impacted by the intended use of the AI system as required by Article X;

(i) For high-risk AI systems, results of the impact assessment on the use of the AI system that is conducted under obligations imposed by Article XX of this Regulation. Where full public disclosure of these results cannot be granted for reasons of privacy and data protection, disclosure must be granted to the national supervisory authority, which in turn must be indicated in the EU database.

(j) A description of how the relevant accessibility requirements set out in Annex I to Directive 2019/882 are met by

the use of the AI system.

Or. en

Amendment 662
Elena Kountoura

Proposal for a regulation
Annex VIII – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	3. The following information shall be provided and thereafter kept up to date by the user with regard to uses of AI systems by public authorities to be registered in accordance with Article 51(3):
	(a) Name, address and contact details of the user;
	(b) Where submission of information is carried out by another person on behalf of the user, the name, address and contact details of that person;
	(c) Name, address and contact details of the authorised representative, where applicable;
	(d) For high-risk AI systems, URL of the entry of the AI system in the EU database by its provider, or, for non-high risk systems, AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;
	(e) Description of the intended purpose of the intended use of the AI system;
	(f) Description of the context and the geographical and temporal scope of application, geographic and temporal, of the intended use of the AI system;
	(g) Basic explanation of design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions

EN

made, also with regard to categories persons or groups of persons on which the system is intended to be used; the main classification choices; and what the system is designed to optimise for and the relevance of the different parameters.

(h) Designation of persons foreseeably impacted by the intended use of the AI system;

(i) If available, results of any impact assessment or due diligence process regarding the use of the AI system that the user has conducted;

(j) Assessment of the foreseeable impact on the environment, including but not limited to energy consumption, resulting from the use of the AI system over its entire lifecycle, and of the methods to reduce such impact;

(k) A description of how the relevant accessibility requirements set out in Annex I to Directive 2019/882 are met by the use of the AI system.

Or. en

Amendment 663
Miapetra Kumpula-Natri
on behalf of the S&D Group

Proposal for a regulation
Annex IX a (new)

Text proposed by the Commission	*Amendment*
	MODALITIES FOR AN EU AI REGULATORY SANDBOXING PROGRAMME
	1. The AI Regulatory Sandboxes shall be part of the EU AI Regulatory Sandboxing Programme ('sandboxing programme') to be established by the Commission in collaboration with Member States.
	2. The Commission shall play a

complementary role, allowing those Member States with demonstrated experience with sandboxing to build on their expertise and the expertise of relevant stakeholders from industry, academia and civil society and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up of these regulatory sandboxes.

3. The criteria for the access to the regulatory sandbox should be transparent and competitive.

4. Participants in the sandboxing programme, in particular small-scale providers, are granted access to pre-deployment services, such as preliminary registration of their AI system, compliance R&D support services, and to all the other relevant elements of the Union's AI ecosystem and other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence; and to other value-adding services such as standardisation documents and certification, consultation and support to conduct impact assessments of the AI systems to fundamental rights, environment or the society at large, an online social platform for the community, contact databases, existing portal for tenders and grant making and lists of EU investors.

5. The sandboxing programme shall, in a later development phase, develop and manage two types of regulatory sandboxes: Physical Regulatory Sandboxes for AI systems embedded in physical products or services and Cyber Regulatory Sandboxes for AI systems operated and used on a stand-alone basis, not embedded in physical products or services

6. The sandboxing programme shall work with the already established Digital

Innovation Hubs in Member States to provide a dedicated point of contact for entrepreneurs to raise enquiries with competent authorities and to seek non-binding guidance on the conformity of innovative products, services or business models embedding AI technologies.

7. One of the objectives of the sandboxing programme is to enable firms' compliance with this Regulation at the design stage of the AI system ('compliance-by-design'). To do so, the programme shall facilitate the development of software tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity as well as minimisation of risks to fundamental rights, environment and the society at large.

8. The sandboxing programme shall be rolled out in a phased fashion, with the various phases launched by the Commission upon success of the previous phase.

9. The sandboxing programme will have a built-in impact assessment procedure to facilitate the review of cost-effectiveness against the agreed-upon objectives. This assessment shall be drafted with input from Member States based on their experiences and shall be included as part of the Annual Report submitted by the Commission to the European Artificial Intelligence Board.

Or. en