Committee on Legal Affairs
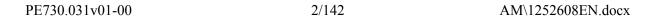
2021/0106(COD)

24.3.2022

AMENDMENTS
310 - 527

Draft opinion
Axel Voss
(PE719.827v01-00)

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))

EN *United in diversity* **EN**

AM_Com_LegOpinion

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Amendment 310
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 development, *deployment* and use of artificial intelligence in conformity with Union values. *Therefore,* 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 values including democracy and rule of law*, and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, *deployment* and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 311
Sergey Lagodinsky

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	(1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform *minimum* legal framework in particular for the development, marketing and use of artificial intelligence in conformity with Union values. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection

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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.

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 justified by the need to ensure the protection of the rights and freedoms of natural persons, or the ethical principles advocated by this Regulation*.

Or. en

Amendment 312
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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 and fundamental rights, and it ensures the free movement of AI-based goods and services cross-border, *while giving* Member States *a clear possibility of* imposing restrictions on the development, marketing and use of AI systems *that could threaten or jeopardise the integrity and sovereignty of those countries and their people*.

Or. fr

Amendment 313
Daniel Buda

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 *harmonised, balanced and* uniform legal framework in particular for the development, marketing and use of artificial intelligence in conformity with *the Union's fundamental* values*, principles, objectives and rights*. 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. ro

Amendment 314
Emmanuel Maurel

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,	(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, *the environment,* safety and fundamental rights, and it ensures the free movement of AI-based goods and services

thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

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. fr

Amendment 315
Sergey Lagodinsky

Proposal for a regulation
Recital 1 a (new)

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

Or. en

Amendment 316
Daniel Buda

Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) This Regulation strongly reaffirms the EU's status as a technology leader and provides the legal mechanisms needed to capitalise on the use of artificial intelligence by guaranteeing positive social and environmental benefits, on the one hand, and essential competitive advantages for Europe's businesses and economy, on the other.

Or. ro

Amendment 317
Daniel Buda

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal	(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, *affecting various activities in areas such as climate change, finance, transport, agriculture, the environment, health, the public sector, internal affairs, quality of life, etc*. 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 *that are not harmonised* may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems*, as well as for private users and direct or indirect beneficiaries of the various AI systems*. A consistent*, harmonised* and high level of protection throughout the Union should therefore be ensured, while

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.

divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform*, clear and transparent* obligations for operators and guaranteeing the uniform *and proportionate* 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. ro

Amendment 318
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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

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, 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). *Nevertheless, respect for the specific legal - and especially constitutional - characteristics of the Member States should enable them to benefit from special derogations if they have a higher level of protection of safety and personal data at national level.* 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. fr

Amendment 319
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple	(2) Artificial intelligence systems (AI systems) can be easily deployed in multiple

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

sectors of the economy and society, including cross border, and circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is *trustworthy and* safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured *in order to achieve trustworthy AI*, while divergences hampering the free circulation of AI systems and related products and services within the internal market should be prevented, by laying down uniform obligations for *developers, deployers and users* 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 320
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *if developed in accordance with relevant ethical principles*. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.
	Or. en

Amendment 321
Emmanuel Maurel

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	Amendment
	(3a) Use of artificial intelligence systems by states or public authorities, or on their behalf, must allow an improvement in access to social benefits and social rights. This technology must be used to combat the major problem of low take-up and to improve living conditions and access to public services. Use of AI systems must be assessed in relation to these effects on social rights. The Member States must not use them in any way that would jeopardise access to social rights or

lead to a deterioration of the social safety net for citizens.

Or. fr

Amendment 322
Sergey Lagodinsky

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*, whether individual, societal or environmental*. Such harm might be material or immaterial. *Harm should be understood as injury or damage to the life, health, physical integrity and the property of a natural or legal person, economic harm to individuals, damage to their environment, security and other aspects defined in the scope of New Approach directives, complemented by collective harms such as harm to society, the democratic process and the environment, or going against core ethical principles. Immaterial harms should be understood as meaning harm as a result of which the affected person suffers considerable detriment, an objective and demonstrable impairment of his or her personal interests and an economic loss calculated having regard, for example, to annual average figures of past revenues and other relevant circumstances. Such immaterial harm can therefore consist of psychological harm, reputational harm or change in legal status. Harm can be caused (i) by single events and (ii) through exposure over time to harmful algorithmic practices, as well as (iii) through action distributed among*

a number of actors where the entity causing the harm is not necessarily that which uses the AI or (iv) through uses of AI which are different than intended for the given system.

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

Amendment 323
Emmanuel Maurel

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*, especially groups that are marginalised and already vulnerable*. Such harm might be material or immaterial and affect people and the environment. *Under the guise of mitigating climate change, through efficient use of resources and energy, AI risks aggravating the situation instead, as additional usage could cancel out any energy savings if usage is not prioritised.*

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

Amendment 324
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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	(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.

may generate risks and cause harm to public interests and rights that are protected by Union law, *and to those of Member States with a strong constitutional tradition, which would go beyond the protection of Union law*. Such harm might be material or immaterial.

Or. fr

Amendment 325
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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*.

Or. en

Amendment 326
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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	(5) A Union legal framework laying down harmonised rules on artificial intelligence *based on ethical principles* 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

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

interests, such as health and safety, *the environment* and the protection of fundamental rights *and values, including democracy and the rule of law*, as recognised and protected by Union law. To achieve that objective, rules regulating *the development,* the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council[33] , and it ensures the protection of ethical principles, as specifically requested by the European Parliament[34] .

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

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

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

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

Or. en

Amendment 327
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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	(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.*

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).

Or. en

Amendment 328
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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

(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.

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 *ordinary legislative procedure* to amend that list.

Or. fr

Amendment 329
Emmanuel Maurel

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) It is important to note that AI systems should respect fundamental principles: non-maleficence, protection of fundamental rights, the trust bestowed on them by end users and system durability. One of the seven key requirements set out by the High-Level Expert Group on Artificial Intelligence is 'societal and environmental wellbeing'. It is therefore crucial to constantly question and evaluate the social and environmental added value of each new technology developed.

Or. fr

Amendment 330
Emmanuel Maurel

Proposal for a regulation
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) For AI systems to guarantee a high level of protection of fundamental rights, it is essential to address the issue of the digital divide. This Regulation will only be effective if it is accompanied by a policy of education, training and awareness as regards these technologies, the biases they entail and the remedies available in the case of errors.

Or. fr

Amendment 331
Daniel Buda

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council[35] , Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[36] and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council[37] .	(7) The notion of biometric data used in this Regulation is in line with and should be *applied and* interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council[35], Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[36] and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council[37].
_____	_____
[35] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection	[35] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection

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

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

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

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

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

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

Or. ro

Amendment 332
Daniel Buda

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to users of AI systems established within the Union.	(10) In order to ensure *a balanced approach in a climate of legal certainty in the European market,* a level playing field *for European businesses* and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to users of

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AI systems established within the Union.

Or. ro

Amendment 333
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 11

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

when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.

third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.

Or. fr

Amendment 334
Emmanuel Maurel

Proposal for a regulation
Recital 12

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 335
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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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 such as democracy and the rule of law*, *a set of ethical principles and* common normative standards for AI systems should be established. Those *principles and* 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 commitments.
	Or. en

Amendment 336
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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. *Moreover, every Member State with a different legal tradition should be able to give priority to ensuring maximum protection for its citizens, particularly on*

the basis of its constitution.

Or. fr

Amendment 337
Sergey Lagodinsky

Proposal for a regulation
Recital 13

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

Or. en

Amendment 338
Emmanuel Maurel

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 commitments.

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Amendment 339
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *based on ethical principles* 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 340
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 341
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 342
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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 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. *Particular attention must be paid to AI systems from third countries to ensure that they are not used as a Trojan horse for non-European interests or that they do not lower our level of protection of data and fundamental rights.*

Or. fr

Amendment 343
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy, *gender equality* and the rights of the child.

Or. en

Amendment 344
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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*	(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. Research for legitimate purposes in relation to such AI systems should 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.

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 345
Sergey Lagodinsky

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	(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 ***non-supervised*** human-machine relations that exposes natural persons to harm and such

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

research is carried out in accordance with recognised ethical standards for scientific research. *If necessary, further flexibilities in order to foster research, and thereby European innovation capacities, should be introduced by Member States.*

Or. en

Amendment 346
Karen Melchior, Yana Toom

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 *without the affected persons' knowledge*, should be forbidden. Such AI systems deploy components individuals cannot perceive or exploit vulnerabilities of *persons or groups of persons with protected characteristics*. They do so with the intention to materially distort the behaviour of a person*. Such distortions are* 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

EN

Amendment 347
Karen Melchior, Yana Toom

Proposal for a regulation
Recital 17

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

Or. en

Amendment 348
Emmanuel Maurel

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

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 the values of equality and justice. Such AI systems evaluate or classify natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are 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. fr

Amendment 349
Sergey Lagodinsky

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 *being core to the Rule of Law*. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such *mass surveillance* 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*

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should be therefore prohibited.

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

Amendment 350
Emmanuel Maurel

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 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.

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

Amendment 351
Sergey Lagodinsky

Proposal for a regulation
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) Within the framework of judicial and administrative proceedings, the responsible authorities should establish

that a practice prohibited under this regulation is not being applied.

Or. en

Amendment 352
Karen Melchior, Svenja Hahn, Yana Toom

Proposal for a regulation
Recital 19

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

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

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

Or. en

Justification

Complete ban on Biometric Mass Surveillance.

Amendment 353
Karen Melchior, Yana Toom

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*	(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 **and** certain threats to the life or physical safety of natural persons or of a terrorist attack.

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.

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

Or. en

Amendment 354
Emmanuel Maurel

Proposal for a regulation
Recital 19

Text proposed by the Commission	Amendment
(19) The use of those systems for the	(19) The use of those systems for the

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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.

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. *In these specific cases, the authorities responsible for using AI systems must ensure that their use does not adversely affect fundamental rights in the field of justice, notably access to justice, the right to a fair trial, the right to an effective remedy and the presumption of innocence.* 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.

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. fr

Amendment 355
Sergey Lagodinsky

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 356

Emmanuel Maurel

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.	(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. *The reference databases must be strictly proportionate and must respect the principle of data minimisation, as provided for in Regulation (EU) 2016/679. Under no circumstances should they be fed with images gathered on a large scale, for example using a large number of images available on social networks.*

Or. fr

Amendment 357
Sergey Lagodinsky

Proposal for a regulation
Recital 21

| *Text proposed by the Commission* | *Amendment* |

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

deleted

Or. en

Amendment 358
Daniel Buda

Proposal for a regulation
Recital 21

| *Text proposed by the Commission* | *Amendment* |

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

(21) 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**,** specific **and, in principle, prior** authorisation by a judicial authority or by **a competent** independent administrative

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.

authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of **demonstrable** 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 **proportionate, 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 **competent** law enforcement authority itself. In addition, the **competent** 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 **and the grounds for its use**.

Or. ro

Amendment 359
Sergey Lagodinsky

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	*deleted*

of justifying authorised use identified in
this Regulation.

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

Amendment 360
Sergey Lagodinsky

Proposal for a regulation
Recital 23

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

EN

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.

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

Amendment 361
Sergey Lagodinsky

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.	(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union*, but also on the environment,* and such limitation minimises any potential restriction to international trade, if any. *Given the rapid path of technological development, but also given the potential changes in the use and the aim of authorised AI systems, regardless of whether they are high-risk or lower risk, the limited list of high-risk systems should nonetheless be subject to permanent review through the exercise of regular assessment as provided in Title III of this Regulation.*

Amendment 362
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 27

<table>
<tr><td>Text proposed by the Commission</td><td>Amendment</td></tr>
<tr><td>(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.</td><td>(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. If they come from third countries, they should be monitored extremely closely by the European supervisory authorities and by independent bodies working in that field. 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.</td></tr>
</table>

Or. fr

Amendment 363
Emmanuel Maurel

Proposal for a regulation
Recital 27

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

Or. fr

Amendment 364
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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*, democracy and the rule of law,* as recognised and protected by Union law. AI systems identified as high-risk should be those that have a significant harmful impact on the health, safety*, the environment,* and fundamental rights of persons*, democracy and the rule of law* in the Union.

Or. en

Amendment 365
Ibán García Del Blanco, René Repasi, Maria-Manuel Leitão-Marques

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. 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	(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, *education,* consumer protection, workers' rights*, gender equality*, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration*, right to protection of intellectual property, cultural diversity*. In addition to those rights, it is important to highlight that children have specific rights as enshrined

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.

in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the harm that an AI system can cause, including in relation to the health and safety of persons *or to the environment, due to the extraction and consumption of natural resources, waste and the carbon footprint*.

Or. en

Amendment 366
Sergey Lagodinsky

Proposal for a regulation
Recital 28 a (new)

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

Or. en

Amendment 367
Sergey Lagodinsky

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The 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.	(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems. *Such classification should take place before the placing onto the market but also during the life-cycle of an AI system.*

Or. en

Amendment 368
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 32

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

EN

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.

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

Or. en

Amendment 369
Kosma Złotowski

Proposal for a regulation
Recital 32

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

Or. en

Amendment 370
Sergey Lagodinsky

Proposal for a regulation
Recital 33

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

Or. en

Amendment 371
Emmanuel Maurel

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. ***The use of 'real-time' remote biometric identification systems should be restricted to certain specific cases laid down in this Regulation, should be strictly proportionate and should be subject to prior authorisation by the national competent authorities.*** In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Amendment 372
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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 oversight. *If they come from third countries, these systems, particularly those that use facial recognition and gather private data, such as Clearview AI, must be monitored extremely closely by the European supervisory authority and independent bodies.*

Or. fr

Amendment 373
Sergey Lagodinsky

Proposal for a regulation
Recital 33 a (new)

Text proposed by the Commission	*Amendment*
	(33a)　Human oversight should target in priority high-risk AI systems, in the aim of serving human-centric objectives. The individuals to whom human oversight is

assigned shall be provided with adequate education and training on the functioning of the application, its capabilities to influence or make decisions, and to have harmful effects, notably on fundamental rights. The persons in charge of the assignment of these individuals shall provide them with relevant staff and psychological support.

Or. en

Amendment 374
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.	(34) As regards the management and operation of critical infrastructure, it is appropriate to classify as high-risk the AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity, since their failure or malfunctioning may put at risk the life and health of persons at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities. *These systems must not be designed or manufactured in a third country and their components must be monitored extremely closely in order to prevent any extra-European control over the sensitive infrastructures of the Member States.*

Or. fr

Amendment 375
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation

EN

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 *rights to gender equality and to not* be discriminated against and perpetuate historical patterns of discrimination.

Or. en

Amendment 376
Karen Melchior, Yana Toom

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	(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 *prohibited*, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. *Due to the reproduction of the inherent biases of our societies*, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate

discrimination.

historical patterns of discrimination.

Or. en

Amendment 377
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 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.	(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 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.

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

Amendment 378
Karen Melchior, Yana Toom

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 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	(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 future career prospects and livelihoods of these persons. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems 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.

privacy.

Amendment 379
Emmanuel Maurel

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 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.	(36) AI systems used in employment, workers management and access to self-employment, notably*, but not exclusively,* for the recruitment and selection of persons, and for task allocation 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. *Use of AI systems for making decisions on promotion and termination and for organising monitoring and monitoring performance and personal behaviour should be classified as a prohibited practice.* 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 be prohibited as they* impact their rights to data protection and privacy.

Amendment 380
Emmanuel Maurel

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	(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 *prohibited*, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant

impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. 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.

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 *prohibited*. 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. fr

Amendment 381
Karen Melchior, Yana Toom

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	(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.

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 *banned*. 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 *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 382
Karen Melchior, Yana Toom

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	(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 *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. In view of the nature of the activities in question and the risks relating thereto, *prohibited* 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, 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, *and* for profiling in the course of

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*.

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 383
Sergey Lagodinsky

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	(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.

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. *Such requirements on transparency and on the explicability of AI decision-making should also help to counter the deterrent effects of digital asymmetry and so-called 'dark patterns' targeting individuals and their informed consent.*

Or. en

Amendment 384
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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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	(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.

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. *None of these systems for sensitive use should be allowed to store outside the Union the data gathered, and any links to third countries should be particularly transparent.*

Or. fr

Amendment 385
Karen Melchior, Yana Toom

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 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	(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 *prohibit* AI systems intended to be used by the competent

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.

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; *and* 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.

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[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).

[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).

[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. en

Amendment 386
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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 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.

(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. ***Every Member State should have the right to exercise full control over the systems they choose and to store the data gathered on their territory.*** 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.

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

[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

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

[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. fr

Amendment 387
Emmanuel Maurel

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 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	(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 **prohibited** 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.

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[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).

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.

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

[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. fr

Amendment 388
Daniel Buda

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	(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 *proportionately*, taking into account the intended purpose of the use of the system and according to the

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management system to be established by the provider.

risk management system to be established *in a clear and accessible manner* by the provider.

Or. ro

Amendment 389
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. *The sovereignty of the Member States must be respected. The Member States must have control over the entire chain of these systems, particularly the data gathered that are not intended to be stored in a third country.* 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. fr

Amendment 390
Emmanuel Maurel

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) Requirements should apply to high-	(43) Requirements should apply to high-

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

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

Or. fr

Amendment 391
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 43

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

Or. en

Amendment 392
Emmanuel Maurel

Proposal for a regulation
Recital 44

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

Or. fr

Amendment 393
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 management system. The technical documentation should be kept up to date.	(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 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, *namely with regard to the extraction and consumption of natural resources,* algorithms *and any pre-determined changes on it and its performance*, data, training, testing and validation processes used as well as documentation on the relevant risk management system *and on the entity that carried out the conformity assessment*. The technical documentation should be kept up to date.

Or. en

Amendment 394
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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	(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

EN

Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date. *If they have been manufactured in third countries, all of these systems must be wholly controlled by the Member State using them, which must ensure continuous monitoring of the entire chain, including manufacture, repair and development.*

Or. fr

Amendment 395
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *easily* 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*. 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 396
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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 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. *All instructions and graphics must be drawn up in the language of the Member State using them, in addition to the usual languages.*

Or. fr

Amendment 397
Emmanuel Maurel

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 **high level** 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.

Or. fr

Amendment 398
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 399
Jiří Pospíšil

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48a) At least two natural persons who verify and confirm the identification resulting from a high-risk AI system referred to in point 1(a) of Annex III should do it independently of each other but that does not mean that these two persons cannot be employees of one institution.

Or. en

Amendment 400
Daniel Buda

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 to the users. *Where applicable, changes in the level of accuracy and accuracy metrics should also be communicated to the users.*

Or. ro

EN

Amendment 401
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 402
Kosma Złotowski

Proposal for a regulation
Recital 51

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

account as appropriate the underlying ICT infrastructure.

notified bodies, competent national authorities and market surveillance authorities accessing the data of providers of high risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Or. en

Amendment 403
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 54

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

Or. fr

Amendment 404
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.	(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use, *which must be drawn up in the user's language in order to avoid any lack of understanding whatsoever,* and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.

Or. fr

Amendment 405
Daniel Buda

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.	(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regards the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities *as regards clarity and accessibility* for users. Users should in particular use high-risk AI systems in accordance with the *accessible and clear* instructions of use and certain other obligations should be provided for *and communicated* with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.

Amendment 406
Emmanuel Maurel

Proposal for a regulation
Recital 59 a (new)

Text proposed by the Commission	*Amendment*
	(59a) In certain cases, AI systems are intended for final beneficiaries rather than users. It is important to guarantee protection of fundamental rights and information for the final beneficiaries, such as healthcare patients, students, consumers, etc. This Regulation should ensure a high level of transparency and respect for the right to information of final beneficiaries, where they differ from users.

Or. fr

Amendment 407
Sergey Lagodinsky

Proposal for a regulation
Recital 61 a (new)

Text proposed by the Commission	*Amendment*
	(61a) As part of the new legal framework on corporate sustainable reporting and due diligence, minimum common standards for the reporting of businesses on the societal and environmental impacts of the AI systems that they develop, sell or distribute shall be established and used at an early stage of the development and life-cycle of AI systems. Such common standard obligations should notably consist in mandatory human rights due diligence rules, thus enabling a level-playing field

among European businesses and non-European businesses operating in the EU.

Or. en

Amendment 408
Emmanuel Maurel

Proposal for a regulation
Recital 64

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

Or. fr

Amendment 409
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) Given the more extensive	(64) Given the more extensive

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

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

Or. en

Amendment 410
Emmanuel Maurel

Proposal for a regulation
Recital 65

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 411
Emmanuel Maurel

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. ***Member States should not create unjustified obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.***	(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market.

Or. fr

Amendment 412
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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 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. ***However, transparency regarding their design, use and possible dangers must be obligatory.***

Or. fr

Amendment 413

Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 414
Emmanuel Maurel

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*	(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 requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system. Such information and notifications should be provided in accessible formats for persons with disabilities *and those who are least familiar with digital technologies*. Further,

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.

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. fr

Amendment 415
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image,	(70) Certain AI systems *used* to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they 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*, which should include a disclaimer,* should be provided in accessible formats for *children, the elderly, migrants and* persons with disabilities. Further, users,

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.

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*, namely the name of the person or entity that created it*.

Or. en

Amendment 416
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *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.

Or. en

Amendment 417
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

EN

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 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

(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 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

to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

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 418
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Recital 73

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

Or. fr

EN

Amendment 419
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 420
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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.	(76) In order to facilitate a smooth, effective and harmonised implementation of this *and other Regulations* a European *Agency for Data and* Artificial Intelligence

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.

should be established. The **Agency** 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 **and other present or future legislations**, 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.

Or. en

Amendment 421
Emmanuel Maurel

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State *one* national authority should be designated as national supervisory authority.	(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State *the* national *data protection* authority should be designated as national supervisory authority.

Or. fr

Amendment 422
Sergey Lagodinsky

Proposal for a regulation

Recital 78

Text proposed by the Commission	*Amendment*

(78)   In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

(78)   In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights *and consumer rights* resulting from the use of their AI systems.

Or. en

Amendment 423
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*

(79)   In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including

(79)   In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including

equality bodies, should also have access to any documentation created under this Regulation.

equality bodies, should also have access to any documentation created under this Regulation. *Where appropriate, national authorities or bodies, which supervise the application of Union law or national law compatible with union law establishing rules regulating the health, safety, security and environment at work, should also have access to any documentation created under this Regulation.*

Or. en

Amendment 424
Sergey Lagodinsky

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including equality bodies, should also have access to any documentation created under this Regulation.	(79) In order to ensure an appropriate and effective enforcement of the requirements and obligations set out by this Regulation, which is Union harmonisation legislation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply in its entirety. Where necessary for their mandate, national public authorities or bodies, which supervise the application of Union law protecting fundamental rights, including equality bodies, should also have access to any documentation created under this Regulation. *A reasonable suspicion of breach of fundamental rights, such as in the case of a consumer complaint or a notification of a breach submitted by a civil society organisation shall be deemed as a sufficient reason for the commencement of an evaluation of an AI system at national level.*

Or. en

EN

Amendment 425
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 development, including on data access infrastructure, semantic and technical interoperability of different types of data.	(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 create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems. *Developers and deployers of all AI systems* should also *draw up codes of conduct in order to ensure and demonstrate compliance with the ethical principles underpinning trustworthy AI as outlined in paragraph 2 of Article 4a*. The Commission *and the European Agency for Data and Artificial Intelligence* 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 426
Emmanuel Maurel

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	(81) The development of AI systems other than high-risk AI systems in

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

accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems. Providers should also apply additional requirements related, for example, to environmental sustainability, accessibility to persons with disability *and those least familiar with digital technologies*, 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. fr

Amendment 427
Ibán García Del Blanco, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 83

Text proposed by the Commission	*Amendment*
(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks.	(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality *and property* of information and data obtained in carrying out their tasks.

Or. en

Amendment 428
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Recital 84

Text proposed by the Commission	*Amendment*
(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European *Data Protection Supervisor* should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.	(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European *Agency for Data and Artificial Intelligence* should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.

Or. en

Amendment 429
Sergey Lagodinsky

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment

procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . *These consultations should involve the participation of a balanced selection of stakeholders, including consumer organisation, associations representing affected persons, businesses representatives from different sectors and sizes, as well as researchers and scientists.* In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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[58] OJ L 123, 12.5.2016, p. 1.

[58] OJ L 123, 12.5.2016, p. 1.

Or. en

Amendment 430
Sergey Lagodinsky

Proposal for a regulation
Recital 86 a (new)

Text proposed by the Commission	*Amendment*
	(86a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the delegation of

powers and the implementing powers of the Commission should be exercised with as much flexibility as possible. The Commission should regularly review Annex III without undue delay, at least every six months, while consulting with the relevant stakeholders, including ethics experts and anthropologists, sociologists, mental health specialists and any relevant scientists and researchers.

Or. en

Amendment 431
Sergey Lagodinsky

Proposal for a regulation
Recital 86 b (new)

Text proposed by the Commission	*Amendment*
	(86b) When adopting delegated or implementing acts concerning high-risk sectors of AI development, notably those raising concerns with respect to ethical principles or entailing risks to the health or safety of humans, animals or plants, or the protection of the environment, Member States should also assume greater responsibility in the decision-making process. In particular, the abstentions of Member States representatives' should be counted within a qualified majority, each Member State representative should give substantive reasons for votes and abstentions, each of their vote and abstention should be accompanied by a detailed justification, on the basis of Regulation XX/XX amending Regulation (EU) No 182/2011.

Or. en

Amendment 432
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
This Regulation lays down:	***In the aim of ensuring a high level of protection of public interests, such as health and safety, of the environment and the protection against risks posed to fundamental rights and against potential harms caused by artificial intelligence, either individual, societal or environmental,*** this Regulation lays down:

Or. en

Amendment 433
Sergey Lagodinsky

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,*** 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 434
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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	(a) harmonised rules for the ***development, deployment*** and the use of artificial intelligence systems ('AI

('AI systems') in the Union; systems') in the Union;

Or. en

Amendment 435
Emmanuel Maurel

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

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

Or. fr

Justification

All AI systems used in the EU, including medium-risk and high-risk systems, must respect a set of common principles laid down in this Regulation, including, in particular, transparency, non-discrimination and fairness.

Amendment 436
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

Text proposed by the Commission	*Amendment*
(d) harmonised transparency rules for **AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and** AI systems **used to generate or manipulate image, audio or video content**;	(d) harmonised transparency rules for **certain** AI systems;

Or. en

Amendment 437

Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
(d) harmonised transparency rules for AI systems *intended to interact with natural persons,* emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;	(d) harmonised transparency rules for AI systems*, including* emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;

Or. en

Amendment 438
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
(e) rules on market monitoring *and* surveillance.	(e) rules on market monitoring*, market* surveillance *and enforcement*.

Or. en

Amendment 439
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(ea) rules on governance

Or. en

Amendment 440

EN

Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(eb) rules for the establishment of an European Agency for Data and Artificial Intelligence.

Or. en

Amendment 441
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	In order to protect public interests such as health, safety, the environment, fundamental rights, democracy and the rule of law, Member States may establish national provisions focusing on certain aspects of use of AI systems that build upon and complement but do not replace, circumvent or contradict the harmonised framework laid down by this Regulation.

Or. en

Amendment 442
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	When justified by significant risks to fundamental rights of persons, including the protection of consumer rights, Member States may introduce regulatory

solutions ensuring a higher level of protection of persons than offered in this Regulation.

Or. en

Amendment 443
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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) *developers and deployers* placing on the market or putting into service AI systems in the Union, irrespective of whether those are established within the Union or in a third country;

Or. en

Amendment 444
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(aa) developers and deployers established or located within the Union for the placing on the market or putting into service AI systems or when the output produced by the system is used in a third country

Or. en

Amendment 445
Sergey Lagodinsky

Proposal for a regulation

EN

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 located *or established* within the Union;

Or. en

Amendment 446
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

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

Or. en

Amendment 447
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	(ca) importers, distributors, and authorised representatives of providers of AI systems;

Or. en

Amendment 448
Daniel Buda

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

EN

Text proposed by the Commission	*Amendment*
	(ca) importers and distributors of AI systems;

Or. ro

Amendment 449
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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

Text proposed by the Commission	*Amendment*
	2a. This Regulation shall not apply to any research and development activity regarding AI systems in so far as such activity does not lead to or entail placing an AI system on the market or putting it into service.

Or. en

Amendment 450
Emmanuel Maurel

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. fr

Amendment 451
Sergey Lagodinsky

Proposal for a regulation

Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation shall not apply to AI systems developed or used exclusively for military *purposes*.	3. This Regulation shall not apply to AI systems developed or used exclusively for *operations having* military *or defence implications carried out by military capabilities under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU)*.

Or. en

Justification

'for national security purposes' (also taken up by Voss in his draft opinion).The exclusion of military, but also of national security purposes, would fall short of covering problematic and high-risk AI systems such as Pegasus. This is one example of AI systems being first developed for national security reasons but used later for broader uses targeting citizens.

Amendment 452
Kosma Złotowski

Proposal for a regulation
Article 2 – paragraph 3

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

Or. en

Amendment 453
Gunnar Beck

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation shall not apply to	3. This Regulation shall not apply to

AI systems *developed or* used exclusively for military purposes.

AI systems used exclusively for military purposes.

Or. en

Amendment 454
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission	*Amendment*
4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States. *In the framework of those agreements, no EU public authority nor any Member State shall obtain, or otherwise make use of, any AI system that is prohibited or limited under this Regulation, unless safeguards similar to the ones established in this provision are adopted by those authorities or organisations*

Or. en

Amendment 455
Kosma Złotowski

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission	*Amendment*
4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within

EN

the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international *cooperation or* agreements for law enforcement and judicial cooperation *or in the context of border checks, asylum and immigration related activities* with the Union or with one or more Member States.

Or. en

Amendment 456
Sergey Lagodinsky

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission	*Amendment*
4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.	4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, *except* where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Or. en

Amendment 457
Gunnar Beck

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission	*Amendment*
4. This Regulation shall not apply to public authorities in a third country nor to *international* organisations falling within the scope of this Regulation pursuant to	4. This Regulation shall not apply to public authorities in a third country nor to *supranational* organisations falling within the scope of this Regulation pursuant to

paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States.

Or. en

Amendment 458
Kosma Złotowski

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.

Or. en

Amendment 459
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission   *Amendment*

5a.   This Regulation shall be without prejudice to Union and national laws on social policies.

Or. en

Amendment 460
Kosma Złotowski

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 461
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(1) 'artificial intelligence system' (AI system) means software that *is developed with one or more of* the techniques and approaches listed in Annex I *and can, for a given set of human-defined objectives, generate* outputs *such as* content, predictions, recommendations*,* or decisions *influencing* the environments *they interact* with;	(1) 'artificial intelligence system' (AI system) means software that *display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals, which:* *(a) receives machine and/or human-based data and inputs;* *(b) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with* the techniques and approaches listed in Annex I*, and* *(c) generates* outputs *in the form of* content *(generative AI systems)*, predictions, recommendations or decisions*, which influence* the environments *it interacts* with;

Or. en

Amendment 462
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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 *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

Amendment 463
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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 *can, in an automated manner*, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

Or. en

Amendment 464
Sergey Lagodinsky

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 *input data and* objectives, generate outputs such as content, predictions, recommendations, or decisions*.*

Or. en

Amendment 465
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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

Text proposed by the Commission	*Amendment*
	(1a) 'autonomy' means that to some degree an AI system operates by interpreting certain input and by using a set of pre-determined objectives, without being limited to such instructions, 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 466
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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

Text proposed by the Commission	*Amendment*
	(1b) 'general purpose AI application'

means AI applications that are able to perform generally applicable functions such as image or speech recognition, audio or video generation, pattern detection, question answering, and translation, are largely customizable and often open source software.

Or. en

Amendment 467
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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) '*developer*' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge*, or that adapts a general purpose AI system to a specific purpose and use*;

Or. en

Amendment 468
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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

Text proposed by the Commission	*Amendment*
(3) 'small-scale provider' means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC[61] ;	*deleted*

_____

EN

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

Or. en

Amendment 469
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(3a) '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 470
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *the* authority *of a deployer*

Or. en

Amendment 471
Emmanuel Maurel

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 *strictly* personal non-professional activity;

Or. fr

Amendment 472
Sergey Lagodinsky

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

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

Or. en

Amendment 473
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(4a) 'final beneficiary' means any natural or legal person, other than an operator, to whom the output of an AI system is intended or provided;

Amendment 474
Sergey Lagodinsky

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 uses the AI system under the authority of the deployer;

Or. en

Amendment 475
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	(4b) 'AI subject' means any natural or legal person that is subject to an AI system interaction or to a treatment of data relating to the subject where it has not been wittingly initiated by that person or where it has been initiated without the person's freely given, specific, informed and unambiguous agreement or consent within the meaning of Regulation (EU) 2016/679;

Or. en

Amendment 476
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 477
Kosma Złotowski

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 478
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

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

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materials and statements, as well as in the technical documentation;

materials and statements, as well as in the technical documentation;

Or. en

Justification

The modification should be made consequentially throughout the text.

Amendment 479
Kosma Złotowski

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

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

Or. en

Amendment 480
Sergey Lagodinsky

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

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

Or. en

**Amendment 481
Kosma Złotowski**

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

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

Or. en

**Amendment 482
Sergey Lagodinsky**

**Proposal for a regulation
Article 3 – paragraph 1 – point 20**

Text proposed by the Commission	*Amendment*
(20) 'conformity assessment' means the process of verifying whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;	(20) 'conformity assessment' means the process of verifying whether the *principles and* requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

Or. en

**Amendment 483
Sergey Lagodinsky**

**Proposal for a regulation
Article 3 – paragraph 1 – point 23**

Text proposed by the Commission	*Amendment*
(23) 'substantial modification' means a change to the AI system following its placing on the market or putting into	(23) 'substantial modification' means a change to the AI system following its placing on the market or putting into

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

service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed *or to its performance, including modifications of the intended purpose of an AI system which is not classified as high-risk and is already placed on the market or put into service.*

Or. en

Amendment 484
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	(33a) 'biometrics-based data' means data resulting from specific technical processing relating to physical, physiological, or behavioural features, 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 identification of a natural person;

Or. en

Amendment 485
Sergey Lagodinsky

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	(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions**,**

intentions of natural persons on the basis of their biometric *data*;

thoughts, states of mind, or intentions of natural persons on the basis of their biometric *or biometrics-based data, whether or not allowing or confirming identification of a natural person*;

Or. en

Amendment 486
Sergey Lagodinsky

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, personality traits* or sexual or political orientation, on the basis of their biometric *or biometrics-based data, whether or not allowing or confirming identification of a natural person*;

Or. en

Amendment 487
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, *and* without prior knowledge of the user of the AI system whether the person will be	(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, without prior knowledge of the user of the AI system whether the person will be

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present and can be identified ;

present and can be identified*, and independent of whether a person identified is an AI subject or interacts directly and purposefully with the system*;

Or. en

Amendment 488
Kosma Złotowski

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

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

Or. en

Amendment 489
Sergey Lagodinsky

Proposal for a regulation
Article 3 – paragraph 1 – point 37

Text proposed by the Commission	*Amendment*
(37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification *all* occur without *a significant delay. This comprises not only instant identification, but also limited short delays in order to avoid circumvention*.	(37) 'real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification occur *on a continuous or large-scale basis over a period of time and* without *limitation to a particular past incident*.

Amendment 490
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 3 – paragraph 1 – point 39

Text proposed by the Commission	*Amendment*
(39) 'publicly accessible space' means any physical place accessible to the public, regardless of whether certain conditions for access may apply;	(39) 'publicly accessible space' means any physical *or virtual* place accessible to the public, regardless of whether certain conditions for access may apply;

Or. en

Amendment 491
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 3 – paragraph 1 – point 39 a (new)

Text proposed by the Commission	*Amendment*
	(39a) 'social scoring' means the evaluation or categorisation of citizens based on their behaviour or personal characteristics;

Or. en

Amendment 492
Emmanuel Maurel

Proposal for a regulation
Article 3 – paragraph 1 – point 42

Text proposed by the Commission	*Amendment*
(42) 'national supervisory authority' means the authority to which a Member State assigns the responsibility for the implementation and application of this	(42) 'national supervisory authority' means the authority to which a Member State assigns the responsibility for the implementation and application of this

Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board;

Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board*. That authority is the Member State's data protection authority*;

Or. fr

Amendment 493
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 3 – paragraph 1 – point 42

Text proposed by the Commission	*Amendment*
(42) 'national supervisory authority' means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European *Artificial Intelligence Board*;	(42) 'national supervisory authority' means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European *Agency for Data and AI (EADA)*;

Or. en

Amendment 494
Emmanuel Maurel

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* that directly or indirectly leads, might have led or might lead to any of the following:

Or. fr

EN

Amendment 495
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 496
Kosma Złotowski

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 497
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(44a)　'AI literacy' means the skills, knowledge and understanding regarding

EN

AI systems that raises are necessary for the compliance with and enforcement of this Regulation

Or. en

Amendment 498
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

Proposal for a regulation
Article 3 a (new)

Text proposed by the Commission	*Amendment*
	Article 3 a
	General Purpose AI
	1. General purpose AI applications shall not be considered as having an intended purpose within the meaning of this Regulation unless those systems have been adapted to a specific intended purpose that falls within the scope of this Regulation.
	2. Any natural or legal person that adapts a general purpose AI application to a specific intended purpose and places it on the market or puts it into service shall be considered the provider and be subject to the obligations laid down in this Regulation.
	3.The initial provider of a general purpose AI application shall, after placing it on the market or putting it to service and without compromising its own intellectual property rights or trade secrets, provide the new provider referred to in paragraph 2 with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.
	4. The initial provider of a general purpose AI application shall only be responsible for the accuracy of the provided information towards the natural or legal person that adapts the general

purpose AI application to a specific intended purpose.

Or. en

Amendment 499
Gunnar Beck, Gilles Lebreton

Proposal for a regulation
Article 4 – title

Text proposed by the Commission	*Amendment*
4 *Amendments to* Annex I	4 *Review clause regarding* Annex I

Or. en

Amendment 500
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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.	*deleted*

Or. en

Amendment 501
Gunnar Beck, Gilles Lebreton

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 list of techniques and approaches listed in Annex I *is reviewed every three years, according to the normal legislative procedure*, in order to *guarantee full democratic oversight*.

Or. en

Amendment 502
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	Amendment
	Article 4 a
	Trustworthy AI
	1. All AI systems in the Union shall be developed, deployed and used in full respect of the EU Charter of Fundamental Rights.
	2. In view of promoting trustworthy AI in the Union, and without prejudice to the requirements set out in Title III for high-risk AI systems, all AI systems shall be developed, deployed and used:
	(a) in a lawful, fair and transparent manner ('lawfulness, fairness and transparency');
	(b) in a manner that ensures that natural persons shall always be able to make informed decisions regarding such systems and these shall never undermine or override human autonomy ('human agency and oversight');
	(c) in a manner that ensures their safe, accurate and reliable performance, with embedded safeguards to prevent any kind

of individual or collective harm ('safety, accuracy, reliability and robustness');

(d) in a manner that guarantees privacy and data protection ('privacy');

(e) in a manner that privileges the integrity and quality of data, including with regard to access ('data governance');

(f) in a traceable, auditable and explainable manner that ensures responsibility and accountability for their outcomes and supports redress ('traceability, auditability, explainability and accountability');

(g) in a manner that does not discriminate against persons or groups of persons on the basis of unfair bias and that includes, to that end, the participation and input of relevant stakeholders('non-discrimination and diversity');

(h) in an environmentally sustainable manner that minimises their environmental footprint, including with regard to the extraction and consumption of natural resources ('environmental sustainability');

(i) in a socially responsible manner that minimises their negative societal impact, especially with regard to social and gender inequalities and democratic processes ('social responsibility');

3. In view of promoting trustworthy AI in the Union, any person or groups of persons affected by the use of an AI system shall have the right to an explanation in accordance with New Article 71, as well as the right to object to an automated decision made solely by an AI system, or relying to a significant degree on the output of an AI system, which produces legal or similarly significant effects concerning them. These rights are without prejudice to Article 22 of Regulation (EU) 2016/679.

4. The ethical principles underpinning trustworthy AI as described in paragraph

2 shall be taken into account by European Standardisation Organisations as outcome-based objectives when they develop harmonised standards for AI systems as referred to in Article 40(2b) and by the European Commission when developing common specifications as referred to in Article 41.

5. Developers and deployers shall specify in the mandatory Codes of Conduct referred to in Article 69, how these principles are taken into account in the course of their activities. For AI systems other than high-risk, developers and deployers should outline any concrete measures implemented to ensure respect for those principles. This obligation is without prejudice to the voluntary application to AI systems other than high-risk of the requirements set out in Title III.

6. In order to demonstrate compliance with this Article, developers and deployers shall, in addition to the obligations set out in paragraphs 5 and after drafting their codes of conduct, complete a trustworthy AI technology assessment. For high-risk AI systems, this assessment shall be part of the requirements under Article 16(a) and 29(4).

Or. en

Amendment 503
Sergey Lagodinsky

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4 a
	Principles applicable to all AI systems
	1. Providers and deployers of AI systems shall respect the following principles:

(a) AI systems must be used in a fair and transparent manner in relation to end-users and individuals who are affected by their use, in particular by avoiding discrimination or causing material distortion of the end-users and individual's economic behaviour, by appreciably impairing their ability to make an informed decision, thereby causing the end-user or individual to take a transactional decision that they would not have taken otherwise;

(b) End-users and individuals affected individually by the use of an AI system have a right to receive an explanation in accordance with Article 4b.

(c) End-users and individuals shall have the right to object to a decision taken solely by an AI system, or relying to a significant degree on the output of an AI system, which produces legal effects concerning him or her, or similarly significantly affects him or her. This paragraph is without prejudice to Article 22 of Regulation 2016/679.

(d) AI systems shall not be used to exploit power and information asymmetries to the detriment of end-users and individuals, regardless of whether such asymmetries already exist or may be created or aggravated by the use of AI systems themselves. In particular, AI systems may not be used to discriminate against end-users and individuals on the basis of the characteristics listed in Article 21 of the European Charter of Fundamental Rights, on the basis of biometrics-based data, as well as on the basis of economic factors;

(e) AI systems must be safe and secure, ensuring a performance that is reliable, accurate, and robust throughout their lifecycle;

(f) AI systems intended to interact with natural individuals shall be designed and developed in such a way that natural individuals are informed that they are

interacting with an AI system, especially where its outputs or behaviour may be reasonably mistaken for that of a human being.

2. Providers of AI systems shall be responsible for, and be able to demonstrate compliance with, the principles established in paragraph 1. This requirement shall apply accordingly to deployers where they have substantially influenced the intended purpose or the manner of operation of the general-purpose AI system.3. The functioning of AI systems shall be regularly monitored and assessed to ensure they respect the rights and obligations set out in EU law.

Or. en

Amendment 504
Sergey Lagodinsky

Proposal for a regulation
Article 4 b (new)

Text proposed by the Commission	*Amendment*
	Article 4 b
	Principles applicable to all AI systems: Explanation of individual decision-making
	1. A decision which is taken by the deployer on the basis of the output from an AI system and which produces legal effects concerning a person, or which similarly significantly affects that person, shall be accompanied by a meaningful explanation of
	(a) the role of the AI system in the decision-making process;
	(b) the logic involved, the main parameters of decision-making, and their relative weight; and
	(c) the input data relating to the affected

person and each of the main parameters on the basis of which the decision was made.

For information on input data under point c) to be meaningful it must include an easily understandable description of inferences drawn from other data if it is the inference that relates to a main parameter.

2. Paragraph 1 shall not apply to the use of AI systems

(a) that have only minor influence within the decision-making process;

(b) that are authorised by law to detect, prevent, investigate and prosecute criminal offences or other unlawful behaviour under the conditions laid down in Article 3(41) and Article 52 of this Regulation;

(c) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or Member State law[A1] , which lays down appropriate other safeguards for the affected person's rights and freedoms and legitimate interests; or

(d) where the affected person has given explicit consent not to receive an explanation.

3. The explanation within the meaning of paragraph 1 shall be provided at the time when the decision is communicated to the affected person.

Or. en

Amendment 505
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 4 b (new)

Text proposed by the Commission	*Amendment*

Article 4 b

AI literacy

1. When implementing this Regulation, the Union and the Member States shall promote measures and tools for the development of a sufficient level of AI literacy, across sectors and groups of developers, deployers and users concerned, including through education and training, skilling and reskilling programmes and while ensuring a proper gender and age balance, in view of allowing a democratic control of AI systems.

2. Developers and deployers of AI systems shall promote tools and take measures to ensure a sufficient level of AI literacy of their staff and any other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the environment the AI systems are to be used in, and considering the persons or groups of persons on which the AI systems are to be used.

3. Such literacy tools and measures shall consist, in particular, of the teaching and learning of basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits and the severity of the possible harm they can cause and its probability of occurrence.

4. A sufficient level of AI literacy is one that contributes to the ability of developers, deployers and users to fully comply with and benefit from trustworthy AI, and in particular with the requirements laid down in this Regulation in Articles 13, 14, 29, 52 and 69.

Or. en

Amendment 506
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
1. The following *artificial intelligence* practices shall be prohibited:	1. The following practices shall be prohibited:

Or. en

Amendment 507
Sergey Lagodinsky

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 *with the effect or likely effect of* materially *distorting* a person's behaviour*, by appreciably impairing the person's ability to make an informed decision, thereby causing the person to take a decision that they would not have taken otherwise,* in a manner that causes or is likely to cause that person or another person *material or non-material harm, including* physical*,* psychological *or economic* harm;

Or. en

Amendment 508
Karen Melchior, Yana Toom

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 materially *distorts* a person's behaviour *without their knowledge.*

Or. en

Justification

"subliminal techniques" is too vague, all AI systems that materially distort a persons behavior without their knowledge should be banned. It is not necessarily possible to know in advance if an AI system will cause harm, therefore it makes more sense to systematically inform the user to avoid harm.

Amendment 509
Emmanuel Maurel

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 in order to materially distort*, voluntarily or for a reasonably foreseeable misuse,* a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm;

Or. fr

Amendment 510
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*

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

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

Or. en

Amendment 511
Sergey Lagodinsky

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

Text proposed by the Commission

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

Amendment

(b) the placing on the market, putting into service or use of an AI system that exploits *or may be reasonably foreseen to exploit* any of the vulnerabilities of *one or several individuals, including ones characteristic of such individuals' known or predicted personality or social or economic situation , with the effect or likely effect of* materially *distorting* the behaviour of a person in a manner that causes or is likely to cause that person or another person *material or non-material harm, including* physical*,* psychological *or economic* harm;

Or. en

Amendment 512
Karen Melchior, Yana Toom

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

Text proposed by the Commission

(b) the placing on the market, putting

Amendment

(b) the placing on the market, putting

EN

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;*

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, *sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, or sexual orientation,* in order to materially distort the behaviour of a person pertaining to that group*.*

Or. en

Justification

Artificial Intelligence solutions risk exploiting vulnerabilities of a much wider range of groups, with data on such groups readily available from sources like social media. I have expanded the list of groups in line with Article 21 of the Charter of Fundamental Rights of the European Union. Furthermore, exploitation of vulnerabilities of these groups is inherently harmful, therefore there is no need to specify.

Amendment 513
Emmanuel Maurel

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 person or* a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person in a manner that causes or is likely to cause that person or another person *economic,* physical or psychological harm;

Or. fr

Amendment 514
Emmanuel Maurel

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 by public authorities or on their behalf*, or by private actors,* 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, *such as preferences, emotions, health or intelligence,* with the social score leading to either or both of the following:

Or. fr

Amendment 515
Karen Melchior, Yana Toom

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

All systems for social scoring should be banned, regardless of if they are operated by public or private entities.

Amendment 516
Sergey Lagodinsky

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 *and social standing* of natural persons over a certain period of time based on *multiple data points on* their social behaviour or known*, inferred* or predicted personal or personality characteristics, *resulting in asocial scoring of natural persons.*

Or. en

Amendment 517
Sergey Lagodinsky

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

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

Or. en

Amendment 518
Kosma Złotowski

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

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

Or. en

Amendment 519
Sergey Lagodinsky

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

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

Or. en

Amendment 520
Kosma Złotowski

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

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

Or. en

EN

Amendment 521
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(ca) the placing on the market, putting into service or use of an AI system in a business or public authority used for making decisions on promotion and termination or for organising monitoring and monitoring performance and behaviour of an employee;

Or. fr

Amendment 522
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cb) the placing on the market, putting into service or use of an AI system designed to detect the emotional state of a natural person, except for specific health reasons, or to classify individuals in groups based on assumed ethnicity, gender, political or sexual orientation, or other grounds on which discrimination is prohibited under Article 21 of the Charter of Fundamental Rights of the European Union;

Or. fr

Amendment 523
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cc) the placing on the market, putting into service or use of an AI system for assessing the creditworthiness of natural persons or establishing their credit score;

Or. fr

Amendment 524
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cd) the placing on the market, putting into service or use, by public authorities or on their behalf, of biometric identification systems that determine allocation of social rights and social benefits;

Or. fr

Amendment 525
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(ce) the placing on the market, putting into service or use of an AI system to be used by law enforcement to make predictions, profile natural persons or assess risks with the end goal of predicting criminal offences;

Or. fr

EN

Amendment 526
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cf) the placing on the market, putting into service or use of an AI system for migration, asylum and border control management to carry out profiling or risk assessment of natural persons or groups in a manner that risks infringing the right of asylum or jeopardising the fairness of migration procedures;

Or. fr

Amendment 527
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cf) the placing on the market, putting into service or use of an AI system to influence consumers' choices for commercial purposes;

Or. fr

EN

Committee on Legal Affairs

2021/0106(COD)

24.3.2022

AMENDMENTS
528 - 746

Draft opinion
Axel Voss
(PE719.827v01-00)

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))

EN

United in diversity

EN

AM_Com_LegOpinion

EN

Amendment 528
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(ch) 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 offending or reoffending or the risk for potential victims of criminal offences;

Or. fr

Amendment 529
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(ci) 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. fr

Amendment 530
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cj) 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. fr

Amendment 531
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(ck) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. fr

Amendment 532
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(cl) 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. fr

Amendment 533
Karen Melchior, Svenja Hahn, Yana Toom

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 for the purpose of law enforcement*.*

Or. en

Justification

Total ban on Biometric Mass surveillance

Amendment 534
Sergey Lagodinsky

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 remote biometric identification systems in publicly accessible spaces*, including where a space is temporarily used to fulfil a public function*

Or. en

Amendment 535
Karen Melchior, Svenja Hahn, Yana Toom

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

Justification

Total ban on Biometric Mass surveillance

Amendment 536
Sergey Lagodinsky

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 537
Kosma Złotowski

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**;	(i) the targeted search for specific potential victims of crime;

Or. en

Amendment 538
Sergey Lagodinsky

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 539
Karen Melchior, Svenja Hahn, Yana Toom

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

Justification

Total ban on Biometric Mass surveillance

Amendment 540
Emmanuel Maurel

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. fr

Amendment 541
Kosma Złotowski

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

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

_____

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

Or. en

Amendment 542
Sergey Lagodinsky

Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

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

_____

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

Or. en

Amendment 543
Karen Melchior, Svenja Hahn, Yana Toom

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

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

_____

⁶² Council Framework Decision

EN

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

Total ban on Biometric Mass surveillance

Amendment 544
Kosma Złotowski

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

Text proposed by the Commission	Amendment
	(iiia) searching for missing persons, especially those who are minors or have medical conditions that affect memory, communication, or independent decision-making skills;

Or. en

Amendment 545
Sergey Lagodinsky

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 emotion recognition systems other than for the personal use of natural persons.

Or. en

Amendment 546

Karen Melchior, Yana Toom

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

Text proposed by the Commission	Amendment
	(da) *practices listed in Annex IIIa;*

Or. en

Justification

An additional annex has been created that will be modifiable through a delegated act. This allows the Commission to respond rapidly in the event of the development of an AI solution that poses an unacceptable risk to fundamental rights, and to ban such practices. Other banned practices remain in the main text as there is no prospect of the risk they pose becoming acceptable, hence the Commission should not be able to freely modify them.

Amendment 547
Karen Melchior, Yana Toom

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 for the purpose of determining access or assigning natural persons to educational and vocational training institutions;*

Or. en

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. This is particularly problematic in an educational environment.

Amendment 548
Karen Melchior, Yana Toom

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

EN

Text proposed by the Commission	*Amendment*
	(dc) 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

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. Cases of discrimination by AI recruitment systems, notably against women, have already resulted in them being discontinued in various companies in the United States.

Amendment 549
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(dd) 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

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. Furthermore, this poses an unacceptable risk to workers' rights. Decisions like this severely affect the lives of those concerned by them, and should only be taken by a Human being.

Amendment 550
Karen Melchior, Yana Toom

Proposal for a regulation

Article 5 – paragraph 1 – point d e (new)

Text proposed by the Commission	*Amendment*
	(de) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

Or. en

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. When it comes to public assistance benefits and services, this could be the difference between a family eating and going hungry. Such decisions should not be taken by Artificial Intelligence.

Amendment 551
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(df) 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

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. This technology has already been deployed in the United States, and has been found to incorrectly report higher chances of re-offence for people of colour. Not only does such technology risk exasperating inequality, but it is also unexplainable, meaning citizens could spend years more in prison for no reason.

Amendment 552
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(dg) 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

Justification

Moved from High-risk to banned practices. Current AI-based systems to establish if a person is lying, or their emotional state, are strongly disputed as being pseudo-scientific, and pose an extreme threat to fundamental rights. Suspects could be incorrectly condemned on the basis of such flawed technologies.

Amendment 553
Karen Melchior, Yana Toom

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

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

Or. en

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. This is particularly problematic in an educational environment. This technology has already been deployed in the United States, and has been

found to incorrectly report higher chances of re-offence for people of colour. Not only does such technology risk exasperating inequality, but it is also unexplainable, meaning citizens could spend years more in prison for no reason.

Amendment 554
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(di) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;

Or. en

Justification

Moved from High-risk to banned practices. These technologies are unexplainable and pose an extreme threat to fundamental rights. Suspects could be incorrectly condemned on the basis of such flawed technologies.

Amendment 555
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(dj) 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

EN

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. Decisions concerning the life and wellbeing of individuals, including the protection of their fundamental rights must be made in a manner that is entirely explainable. This is not possible with AI based solutions

Amendment 556
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(dk) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;

Or. en

Justification

Moved from High-risk to banned practices. AI only repeats what we have, meaning it will exasperate existing inequalities. Decisions concerning the life and wellbeing of individuals, including the protection of their fundamental rights must be made in a manner that is entirely explainable. This is not possible with AI based solutions

Amendment 557
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	1a. Unless with the free, informed, and withdrawable consent of the natural persons involved, the collection or generation of data used in AI systems throughout their lifecycle, including training, validation and testing shall be

prohibited when serving the practices listed in paragraph 1 of this Article.

Or. en

Amendment 558
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	1a. The prohibitions under this Article are without prejudice to other prohibitions that may apply where an artificial intelligence practice violates Union and national laws, including data protection law, non-discrimination law, consumer protection law, and competition law.

Or. en

Amendment 559
Sergey Lagodinsky

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 560
Emmanuel Maurel

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.	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. *This use shall be strictly proportionate and shall not result in any unjustified infringement of the protection of privacy and the fundamental rights protected by Union law.*

Or. fr

Amendment 561
Emmanuel Maurel

Proposal for a regulation
Article 5 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The use of reference databases used by the authorities as part of 'real-time' remote biometric identification systems in publicly accessible spaces shall be strictly limited and proportionate to the objective of the search. Those databases must respect the principle of data minimisation, as provided for in Regulation (EU) 2016/679. Databases containing a large volume of data without any distinction in terms of relevance to the objective are strictly prohibited. Large-scale use of data available publicly to establish huge databases is strictly prohibited. The authorities shall refrain from using reference databases that would infringe fundamental rights, especially the right to privacy.

Or. fr

Amendment 562
Emmanuel Maurel

Proposal for a regulation
Article 5 – paragraph 2 – subparagraph 1 b (new)

Text proposed by the Commission	*Amendment*
	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 under no circumstances infringe the freedom of assembly and association or political pluralism. This use cannot be used to identify individuals when exercising their rights.

Or. fr

EN

Amendment 563
Sergey Lagodinsky

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 564
Emmanuel Maurel

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

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.	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. *Such situations must continue to be exceptions. Existing national law must be duly applied in these exceptional cases in order to guarantee respect for fundamental rights and freedoms. Where prior authorisation was not granted, the national competent authorities shall subsequently assess whether use of a 'real-time' biometric identification system in publicly accessible spaces was justified.*

Or. fr

Amendment 565
Emmanuel Maurel

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

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	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

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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.

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 *strictly proportionate* use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

Or. fr

Amendment 566
Sergey Lagodinsky

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 567
Emmanuel Maurel

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.	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. *The Member States shall put in place the safeguards needed to ensure respect for fundamental rights.*

Or. fr

Amendment 568
Karen Melchior, Yana Toom

Proposal for a regulation
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Amendments to Annex IIIa
	1. The Commission is empowered to

adopt delegated acts in accordance with Article 73 to update the list in Annex IIIa by adding prohibited AI practices where such practices pose an unacceptable risk to fundamental rights.

2. When assessing for the purposes of paragraph 1 whether an AI system poses an unacceptable risk to fundamental rights, the Commission shall take into account the following criteria:

(a) the intended purpose of the AI system;

(b) the extent to which an AI system has been used or is likely to be used;

(c) the extent to which the use of an AI system has already had an adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such an impact, as demonstrated by reports or documented allegations submitted to national competent authorities;

(d) the potential extent of such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;

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

(f) the extent to which potentially adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, or age;

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

Or. en

Justification

This amendment gives the Commission the possibility to amend by way of delegated act the annex listing additional banned practices. This future-proofs the legislation.

Amendment 569
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	-1. ***The risk classification of an AI system shall be commensurate with the level of the risk to freedoms and fundamental rights of persons, as well as societal and environmental impacts, associated with its development and use, in terms of the probability and impact of an incident.***

Or. en

Amendment 570
Kosma Złotowski

Proposal for a regulation
Article 6 – paragraph 1 – point a

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

Or. en

Amendment 571
Sergey Lagodinsky

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.	(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II*, or where the uses of safety component is the AI system, or the AI system itself as a product lack sufficient clarity or are undetermined*.

Or. en

Amendment 572
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	(ba) If, in the course of the assessment prescribed by Article 6b of this Regulation, the AI system or its operation is found to result in a high risk to the rights and freedoms of natural persons.

Or. en

Amendment 573
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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	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.

systems referred to in Annex III shall also be considered high-risk *due to their risk to cause harm to health, safety, the environment, fundamental rights or to democracy and the rule of law*.

Or. en

Amendment 574
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(2a) In addition to the high-risk AI systems referred to in paragraphs 1 and 2, AI systems shall be considered high-risk if the final beneficiaries total more than 20 million citizens across the EU or 50% of the population of a given Member State, or whose users have more than 20 million customers or beneficiaries in the EU who are affected by the system.

Or. fr

Amendment 575
Kosma Złotowski

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

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

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overall system.

Or. en

Amendment 576
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article 6a
	Preliminary risk self-assessment
	1. Deployers shall be required to carry out a preliminary self-assessment in order to assess whether their AI systems fall under the scope of Article 5 or Article 6.
	2. In the assessment referred to in paragraph 1, deployers shall include the following elements:
	(a) description of the AI system, including its purpose, and of the persons or groups of purposes it may impact, as well as of the degree of human agency and oversight over its outcomes;
	(b) an analysis of the social and economic risks and benefits of the use of the AI system with regard to its purpose, as well as of the existing safeguards concerning the distribution of benefits and costs associated with its use;
	(c) an assessment of any potential material or immaterial risks of harm, including likelihood and severity, to health, safety, the environment, fundamental rights and to democracy and rule of law, this assessment shall include:
	(i) existing studies or reports published by national competent authorities about previous evaluations;
	(ii) whether and to what extent the

persons or groups of persons affected by the AI system are dependent on its outcome and could opt-out from it;

(iii) whether and to what extent the outcome produced by the AI system is reversible;

(iv) whether and to what extent the persons or group of persons affected by the AI system are in a vulnerable position in relation to its deployer, including due to an imbalance of power, knowledge, economic or social circumstances, gender, age, etc.

(v) whether and to what extent any misuse of the AI system could have a negative impact on persons, group of persons and society at large;

(d) the measures taken to address and mitigate identified risks.3.

3. The European Agency for Data and AI shall provide guidelines for self-assessments according to paragraph 3, as well outline best practices in order to serve as additional support to comply with this Article. National competent authorities shall also provide direct consultation for deployers in this regard.

4. Deployers shall keep a detailed record, including all relevant documentation, of the preliminary self-assessment at the disposal of the national competent authorities during the lifecycle of the AI system.

5. Should the self-assessment conclude that an AI system does not comply with this Regulation, the deployer shall immediately take any necessary measures to ensure compliance with the Regulation.

6. For the purposes of carrying out the trustworthy AI technology assessment foreseen in paragraph 6 to Article 4a, deployers may, in addition to their codes of conduct, use the assessment and documentation required in the Article to

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carry out that assessment.

Or. en

Amendment 577
Sergey Lagodinsky

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article 6a
	Preliminary self-assessment
	1. Before the conformity assessment procedure foreseen in Articles 43 for high-risk AI systems and 51a for other than high-risk AI systems, the provider of the AI system shall carry out a preliminary self-assessment to assess whether:
	(a) the intended purpose, reasonably foreseeable misuse or potential use of their AI system would constitute a prohibited practice under Articles 5;
	(b) the intended purpose, potential use or reasonably foreseeable misuse of the AI system could have a negative impact on fundamental rights and freedoms, as contemplated in Article 6;
	(c) the AI system is classified as 'high-risk AI system' as contemplated in Article 6;
	2. The provider of the AI system shall keep a detailed record, including all relevant documentation, of that self-assessment at the disposal of the national competent authorities during the lifespan of the concerned AI system.
	3. Where the preliminary self-assessment yields non-compliance of the AI system with this Regulation, in particular due to a breach of Article 5, the provider shall, without delay, take

measures to ensure compliance of the
concerned AI system with this Regulation.

Or. en

Amendment 578
Gunnar Beck, Gilles Lebreton

Proposal for a regulation
Article 7 – title

Text proposed by the Commission	*Amendment*
7 *Amendments to* Annex III	7 *Review clause regarding* Annex III

Or. en

Amendment 579
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

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

Or. en

Amendment 580
Daniel Buda

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

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

Or. ro

Amendment 581
Gunnar Beck, Gilles Lebreton

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 list *of* high-risk AI systems *listed in Annex III is reviewed every three years, according to the normal legislative procedure, in order to guarantee full democratic oversight,* where both of the following conditions are fulfilled:

Or. en

Amendment 582
Karen Melchior, Yana Toom

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

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

Or. en

Justification

In the original text, the Commission is only given the possibility to add High-risk AI applications to the existing categories in Annex III, this limits their ability to react to new technological developments. This amendment gives the Commission the ability to add new high-risk AI systems outside of the existing categories

Amendment 583
Karen Melchior, Yana Toom

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

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

Or. en

Justification

In the original text, the Commission is only given the possibility to add High-risk AI applications to the existing categories in Annex III, this limits their ability to react to new technological developments. This amendment gives the Commission the ability to add new high-risk AI systems outside of the existing categories

Amendment 584
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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 ***on*** Annex III

Or. en

Amendment 585
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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**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*, 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 586
Kosma Złotowski**

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

Or. en

**Amendment 587
Emmanuel Maurel**

**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 health and safety, **an economic risk** 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. fr

Amendment 588
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 **environment,** health and safety or a risk of adverse impact on fundamental rights **or 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 589
Kosma Złotowski

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	2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health**, natural**

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:

environment and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:

Or. en

Amendment 590
Gunnar Beck, Gilles Lebreton

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 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 following criteria *shall be taken into account*:

Or. en

Amendment 591
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

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

Or. en

Amendment 592
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *environment,* health and safety or adverse impact on the fundamental rights *or democracy and rule of law* 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 593
Kosma Złotowski

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

Or. en

Amendment 594
Emmanuel Maurel

EN

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 health*,* safety *and the 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. fr

Amendment 595
Emmanuel Maurel

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 in relation to the risks posed by an AI system, *including* claims for *material or non-material* damages;

Or. fr

Amendment 596
Gunnar Beck, Gilles Lebreton

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

Text proposed by the Commission	*Amendment*
	(ha) The share of public funding the development of the AI systems receives from third-country investors of public authorities.

Justification

The evolution of foreign (direct) investment in European and third-country AI systems should be adequately scrutinized. Foreign investment by hostile or potentially hostile third countries should be able to lead to banning the use of such AI systems on the EU internal market.

Amendment 597
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(ha) the general capabilities and the functionalities of the AI system independent of its intended purpose;

Or. fr

Amendment 598
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(hb) the extent of the availability and use of proven technical solutions and mechanisms for the monitoring, reliability and 'correctability' of the AI system;

Or. fr

Amendment 599
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(hc) the potential for misuse and malicious use of the AI system and the technology underpinning it;

Or. fr

Amendment 600
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	2a. The assessment referred to in paragraph 2 shall be conducted by the Commission without undue delay and under the consultation conditions laid down in this regulation, notably in Article 73.

Or. en

Amendment 601
Sergey Lagodinsky

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

Or. en

Amendment 602

Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 updating*, and in any event 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 603
Sergey Lagodinsky

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. It shall comprise the following steps:

Or. en

Amendment 604
Sergey Lagodinsky

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

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

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

measures in accordance with the provisions of the following paragraphs.

Or. en

Amendment 605
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(da) drawing up of the mandatory Codes of Conduct referred to in Article 69 taking into account the ethical principles laid down in new Article 4a.

Or. en

Amendment 606
Kosma Złotowski

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

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

Or. en

Amendment 607
Sergey Lagodinsky

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 *and the reasoned judgements made* shall be communicated to the user.

Or. en

Amendment 608
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
(b) where appropriate, implementation of *adequate* mitigation and control measures *in relation to* risks that cannot be eliminated*;*	(b) where appropriate, implementation of mitigation and control measures *addressing* risks that cannot be eliminated

Or. en

Amendment 609
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(ca) *the provision of a sufficient level of AI literacy as outlined in new Article 4b to deployers and users.*

Or. en

Amendment 610
Sergey Lagodinsky

Proposal for a regulation
Article 9 – paragraph 5

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

Or. en

Amendment 611
Sergey Lagodinsky

Proposal for a regulation
Article 9 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve *that purpose*.	6. Testing procedures shall be suitable to achieve the intended purpose of the AI system*, and its reasonably foreseeable misuse,* and do not need to go beyond what is necessary to achieve *this*.

Or. en

Amendment 612
Sergey Lagodinsky

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*:*
	(a) be accessed by or have an impact on children*, or*
	(b) have an impact on the environment.

Or. en

Amendment 613
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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, migrants or other vulnerable groups*.

Or. en

Amendment 614
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *and fairness* criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 615
Sergey Lagodinsky

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 *practices throughout the entire lifecycle of the AI system* . Those practices shall concern in particular,

Or. en

Amendment 616
Kosma Złotowski

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

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

Or. en

Amendment 617
Kosma Złotowski

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

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

Or. en

Amendment 618
Kosma Złotowski

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

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

Or. en

Amendment 619
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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*, including where data outputs are used as an input for future operations*;

Or. en

Amendment 620
Emmanuel Maurel

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;

Or. fr

Amendment 621
Kosma Złotowski

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

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

Or. en

Amendment 622
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

Text proposed by the Commission	*Amendment*
(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.	(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed*, as well as any other relevant variables*.

Amendment 623
Sergey Lagodinsky

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 how those gaps and shortcomings can be addressed.

Or. en

Amendment 624
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(ga) the purpose and the environment in which the system is to be used;

Or. en

Amendment 625
Emmanuel Maurel

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	3. Training, validation and testing data sets shall be relevant, *sufficiently 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

characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

to be used. *These data sets shall consist of sufficiently large volumes of data, and they shall take account of all of the relevant aspects of gender, social, geographical and ethnic group, and other grounds for discrimination prohibited under Union law. They shall cover all the necessary relevant scenarios in order to avoid hazardous situations.* These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. fr

Amendment 626
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 extend possible*, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof. *If occasional inaccuracies cannot be avoided, the system shall indicate, to the best extent possible, the likeliness of errors and inaccuracies to deployers and users through appropriate means.*

Or. en

Amendment 627
Kosma Złotowski

Proposal for a regulation
Article 10 – paragraph 3

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

Or. en

Amendment 628
Sergey Lagodinsky

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, free of errors and *statistically* 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 629
Kosma Złotowski

Proposal for a regulation
Article 10 – paragraph 4

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

Or. en

Amendment 630
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

Or. en

Amendment 631
Sergey Lagodinsky

Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission	*Amendment*
5. To the extent that it is strictly necessary for the purposes of ensuring bias	5. To the extent that it is 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.

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 use of state-of-the-art security*, data minimisation, anonymisation* and pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued*, as well as other measures preserving privacy, confidentiality, integrity, availability, resilience, authenticity and trustworthiness, non-repudiation, accountability, auditability, and enabling data subjects the exercise of their data subjects' rights*.

Or. en

Amendment 632
Kosma Złotowski

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-	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-

EN

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

preserving measures, such as pseudonymisation, encryption *or biometric template protection technologies* where anonymisation may significantly affect the purpose pursued.

Or. en

Amendment 633
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

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

Text proposed by the Commission	*Amendment*
1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.	1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date. *It must be drawn up in the language of the system user, in addition to the usual languages allowing it to be read by as many people as possible.*

Or. fr

Amendment 634
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.	1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date *throughout its entire lifecycle, and where appropriate, beyond* .

Or. en

Amendment 635
Ibán García Del Blanco, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.	The technical documentation shall be drawn up*, without unduly compromising intellectual property rights or trade secrets,* in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Or. en

Amendment 636
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 systems *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 enabling the automatic recording of events ('logs') *throughout the* AI systems *lifecycle*. Those logging capabilities shall conform to recognised standards or common specifications.

Or. en

Amendment 637
Kosma Złotowski

Proposal for a regulation

Article 12 – paragraph 2

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

Or. en

Amendment 638
Ibán García Del Blanco, Tiemo Wölken, René Repasi

Proposal for a regulation
Article 12 – paragraph 2

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

Or. en

Amendment 639
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 12 – paragraph 3

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

referred to in Article 61.

referred to in Article 61 *and the monitoring of the operation of high-risk AI systems referred to in Article 29 (4)*.

Or. en

Amendment 640
Kosma Złotowski

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

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

Or. en

Amendment 641
Sergey Lagodinsky

Proposal for a regulation
Article 13 – title

Text proposed by the Commission	*Amendment*
13 Transparency and provision of information to users	13 Transparency and provision of information to users *and AI subjects*

Or. en

Amendment 642
Sergey Lagodinsky

Proposal for a regulation
Article 13 – paragraph 1

EN

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.	1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title. *Where individuals are passively subject to AI systems (AI subjects), information to ensure an appropriate type and degree of transparency shall be made publicly available, with full respect to the privacy, personality, and related rights of subjects.*

Or. en

Amendment 643
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users *to* interpret the system's output and use it appropriately*. An appropriate type and degree of transparency shall be ensured*, with a view to achieving compliance with the relevant obligations *of the user and of the provider* set out in Chapter 3 of this Title.	1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable *developers, deployers,* users *and other relevant stakeholders to easily* interpret the system's *functioning and* output and use it appropriately *on the basis of informed decisions* , with a view to achieving compliance with the relevant obligations set out in Chapter 3 of this Title.

Or. en

Amendment 644
Brando Benifei

Proposal for a regulation
Article 13 – paragraph 1

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

Or. en

Amendment 645
Emmanuel Maurel

Proposal for a regulation
Article 13 – paragraph 1

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

Or. fr

Amendment 646
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 13 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Any person or groups of persons subject to a decision taken by a deployer or user on the basis of output from an AI System shall be informed where such decision produces legal or otherwise significant effects, including when their health and safety or the respect for their fundamental rights is affected.

Or. en

Amendment 647
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 13 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. In the cases referred to in paragraph 1, the persons or groups of person affected shall have the right to request an explanation in line with New Article 71.

Or. en

Amendment 648
Kosma Złotowski

Proposal for a regulation
Article 13 – paragraph 2

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

comprehensible to users *to assist them in operating and maintaining the AI system, taking into consideration the system's intended purpose and the expected audience for the instructions*.

Or. en

Amendment 649
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.	2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users *and, in particular, that is drawn up in the user's language*.

Or. fr

Amendment 650
Sergey Lagodinsky

Proposal for a regulation
Article 13 – paragraph 2

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

Or. en

EN

Amendment 651
Brando Benifei

Proposal for a regulation
Article 13 – paragraph 2

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

Or. en

Amendment 652
Emmanuel Maurel

Proposal for a regulation
Article 13 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The providers shall be available to users and authorities to answer their questions and provide any clarifications they might seek, in particular to ensure that use of the AI system respects the fundamental rights and law of the Union.

Or. fr

Amendment 653
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	(aa) where it is not the same as the deployer, the identity and the contact

details of the entity that carried out the conformity assessment and, where applicable, of its authorised representative;

Or. en

Amendment 654
Kosma Złotowski

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

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

Or. en

Amendment 655
Brando Benifei

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

Text proposed by the Commission	*Amendment*
(i) *its intended purpose*;	(i) *any known or reasonably foreseeable use*;

Or. en

Justification

even providers of general purpose AI are and should be aware of different foreseeable uses of their AI systems.

Amendment 656

EN

Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

Text proposed by the Commission	*Amendment*
(i) its *intended* purpose;	(i) its purpose;

Or. en

Amendment 657
Karen Melchior, Yana Toom

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

Text proposed by the Commission	*Amendment*
	(ia) An overview of different inputs taken into account by the Artificial Intelligence solution when making decisions.

Or. en

Justification

To provide transparency both to operators, and end users, the criteria used by an AI to make decisions should be transparent.

Amendment 658
Kosma Złotowski

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

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

and cybersecurity;

accuracy, robustness and cybersecurity;

Or. en

Amendment 659
Brando Benifei

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

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

Or. en

Amendment 660
Ibán García Del Blanco, René Repasi, Maria-Manuel Leitão-Marques

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

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

Or. en

Amendment 661
Emmanuel Maurel

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

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

Or. fr

Amendment 662
Sergey Lagodinsky

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

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

Or. en

Amendment 663
Brando Benifei

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

Text proposed by the Commission	*Amendment*

(iv) its performance as regards the persons or groups of persons on which the system is intended to be used;	(iv) its performance as regards the persons or groups of persons on which the system is intended *or reasonably foreseeable* to be used;

Or. en

Amendment 664
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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

Text proposed by the Commission	*Amendment*
(iv) its performance as regards the persons or groups of persons on which the system is *intended* to be used;	(iv) its performance as regards the persons or groups of persons on which the system is to be used;

Or. en

Amendment 665
Brando Benifei

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

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

Or. en

Amendment 666
Ibán García Del Blanco, Tiemo Wölken, René Repasi

Proposal for a regulation

EN

Article 13 – paragraph 3 – point b – point v

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

Or. en

Amendment 667
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
(c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;	(c) the changes to the high-risk AI system and its performance*, including its algorithms,* which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;

Or. en

Amendment 668
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
(e) the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.	(e) the expected lifetime of the high-risk AI system*, its level of extraction and consumption of natural resources,* and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.

Amendment 669
Kosma Złotowski

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

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

Or. en

Amendment 670
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	3a. In order to comply with the obligations established in this Article, developers and deployers shall ensure a sufficient level of AI literacy in line with New Article 6.

Or. en

Amendment 671
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*

3b.   Member States may adopt measures beyond those listed in this Article insofar as they are not in contradiction with, result in the circumvention of or otherwise jeopardize the harmonised application of the requirements laid out in this Regulation, irrespective of whether they would apply to high-risk AI systems or all AI systems.

Or. en

Amendment 672
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 14 – title

Text proposed by the Commission	*Amendment*
14 Human oversight	14 Human *agency and* oversight

Or. en

Amendment 673
Brando Benifei

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 *with the necessary competence, training and authority to exercise that function,* during the period in which the AI system is in use.

Or. en

Justification

wording in line with the Platform Workers Directive

Amendment 674
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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 *at all times* be effectively overseen *with agency* by natural persons during the period in which the AI system is in use *and irrespectively of their specific characteristics*.

Or. en

Amendment 675
Sergey Lagodinsky

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*, and to allow for thorough investigation after an incident*.

Or. en

Amendment 676
Ibán García Del Blanco, René Repasi, Maria-Manuel Leitão-Marques

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 *unethical* risks to *the environment,* health, safety*,* fundamental rights *and democracy or the rule of law* that may emerge when a high-risk AI system is used in accordance with its purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter *and where decisions based solely on automated processing by AI systems produce legal or otherwise significant effects on the persons or groups of persons on which the system is to be used*.

Or. en

Amendment 677
Brando Benifei

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Human oversight shall aim at preventing or minimising the risks to health, safety *or* fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.	2. Human oversight shall aim at preventing or minimising the risks to health, safety*,* fundamental rights*, democracy, rule of law or the environment* that may emerge when a high-risk AI system is used in accordance with its intended purpose *or reasonably foreseeable use,* or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Amendment 678
Sergey Lagodinsky

Proposal for a regulation
Article 14 – paragraph 2

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

Or. en

Amendment 679
Emmanuel Maurel

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 the risks to health, safety or fundamental rights that 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. fr

Amendment 680

EN

Emmanuel Maurel

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 oversight shall be ensured through all of the following measures:

Or. fr

Amendment 681
Kosma Złotowski

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

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

Or. en

Amendment 682
Kosma Złotowski

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

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

Or. en

Amendment 683
Sergey Lagodinsky

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 *that allows the system to come to a halt in a safe state*.

Or. en

Amendment 684
Sergey Lagodinsky

Proposal for a regulation
Article 14 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The individuals to whom human oversight is assigned shall be provided with adequate education and training ,as well as relevant staff and psychological support.

Or. en

Amendment 685
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or	5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or

decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.

decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons **with the necessary competence, training and authority**.

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

Amendment 686
Brando Benifei

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For high-risk AI systems referred to in *point 1(a)* of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the *identification* resulting from the system unless this has been verified and confirmed by at least two natural persons.	5. For high-risk AI systems referred to in *areas 1, 6 and 7* of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the *output* resulting from the system unless this has been verified and confirmed by at least two natural persons.

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

Amendment 687
Sergey Lagodinsky

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the *identification resulting* from the system unless this has been verified and confirmed by at least two natural persons*.*	5. For high-risk AI systems referred to in point 1(a) *and 1(b)* of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the *output* from the system unless this has been verified and confirmed by at least two natural persons

Amendment 688
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 14 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. In order to comply with the obligations established in this Article, developers and deployers shall ensure a sufficient level of AI literacy in line with New Article 6.

Or. en

Amendment 689
Sergey Lagodinsky

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, an appropriate level of accuracy, *reliability,* robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Or. en

Amendment 690
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*

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

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

Or. en

Amendment 691
Sergey Lagodinsky

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

Or. en

Amendment 692
Sergey Lagodinsky

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

Amendment 693
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	(aa) *include name and contact information;*

Or. en

Amendment 694
Sergey Lagodinsky

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 high-risk AI systems *for a period of at least ten years, or as long as is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law* ;

Or. en

Amendment 695
Gunnar Beck, Gilles Lebreton

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

Text proposed by the Commission	*Amendment*
	(ja) *Provide an overview of all investors, either via direct participation, venture capital or bank financing,*

participating in the development, production and distribution of the AI system.

Or. en

Justification

Financial transparency should be of paramount importance, also in the assessment of the risk of foreign control over an AI system.

Amendment 696
Gilles Lebreton, Jean-Paul Garraud, Gunnar Beck

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV.	1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV. *One of the languages used must always by the end user's language in order to prevent any misunderstandings.*

Or. fr

Amendment 697
Sergey Lagodinsky

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Providers of high-risk AI systems shall draw up the technical documen-tation referred to in Article 11 in accordance with Annex IV.	1. Providers of high-risk AI systems shall draw up the technical documen-tation referred to in Article 11 in accordance with Annex IV *and make it available at the request of a national competent authority*.

Or. en

Amendment 698
Emmanuel Maurel

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.	1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49. *The conformity assessment must be published.*

Or. fr

Amendment 699
Sergey Lagodinsky

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.	*deleted*

Amendment 700
Emmanuel Maurel

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

Or. fr

Amendment 701
Sergey Lagodinsky

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 by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.	2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs **pursuant to Article 16(1)(d)** automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.

Or. en

Amendment 702
Sergey Lagodinsky

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

Or. en

Amendment 703
Emmanuel Maurel

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.	Providers of high-risk AI systems which consider*,* have reason to consider *or have been notified by a supervisory authority* 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.

Or. fr

Amendment 704

EN

Sergey Lagodinsky

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

Or. en

Amendment 705
Sergey Lagodinsky

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 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 *competent authorities and the* provider or the importer of the system, as applicable, to that effect.

Or. en

Amendment 706
Sergey Lagodinsky

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

Or. en

Amendment 707
Sergey Lagodinsky

Proposal for a regulation
Article 27 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate	5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate

with that *national* competent authority on any action taken by that authority.

with that competent authority on any action taken by that authority.

Or. en

Amendment 708
Sergey Lagodinsky

Proposal for a regulation
Article 29 – title

Text proposed by the Commission	*Amendment*
Obligations of *users* of high-risk AI systems	Obligations of *deployers* of high-risk AI systems
	(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Or. en

Amendment 709
Sergey Lagodinsky

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Users of high-risk AI systems shall *use* such systems in accordance with the instructions of use accompanying the systems*, pursuant to paragraphs 2 and 5*.	1. Users of high-risk AI systems shall *take appropriate organisational measures and ensure that use of* such systems *takes place* in accordance with the instructions of use accompanying the systems *and enables human oversight and decision-making*.

Or. en

Amendment 710
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
	1a. In order to comply with the obligations established in this Article, as well as to be able to justify their possible non-compliance, deployers of high-risk AI systems shall ensure a sufficient level of AI literacy in line with New Article 6.

Or. en

Amendment 711
Kosma Złotowski

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

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

Or. en

Amendment 712
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	1a. Deployers shall identify the categories of natural persons and groups likely to be affected by the system before putting it into use.

Or. en

Amendment 713

Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
	1b. Human oversight following paragraph 1 shall be assigned to natural persons having the necessary competences, training, authority and independence.

Or. en

Amendment 714
Emmanuel Maurel

Proposal for a regulation
Article 29 – paragraph 4 – introductory part

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

Or. fr

Amendment 715

Sergey Lagodinsky

Proposal for a regulation
Article 29 – paragraph 5 – introductory part

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

Or. en

Amendment 716
Emmanuel Maurel

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

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

Or. fr

Amendment 717
Sergey Lagodinsky

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29a

Fundamental rights impact assessments for high-risk AI systems

1.   Deployers of high-risk AI systems shall assess a system's fundamental rights impact in the context of its use before putting it into use. This assessment shall include at least the following:

(a)   the intended purpose;

(b)   the intended geographic and temporal scope;

(c)   an assessment of the legality in accordance with Union law, fundamental rights, and accessibility requirements;

(d)   an assessment of the likely impact for the public interest and on fundamental rights, including any indirect impacts or consequences;

(e)   an assessment of the likely impact on marginalised or underrepresented persons or groups;

(f)   the system's impact on the environment, including the energy consumption of all phases of the system's lifecycle;

(g)   adequate measures to mitigate risks and harm, and an assessment of their likely effectiveness.

2.   If measures pursuant to point g of paragraph 1 cannot be identified, the system shall not be put into use. Market surveillance authorities should take this information into account when investigating systems which present a risk.

3.   The obligation pursuant to paragraph 1 applies to each new deployment of the high-risk AI system.

4.   The deployer shall submit the impact assessment to the competent authorities and relevant stakeholders and allow for a period of six weeks for these to respond. The deployer shall take these responses into account before putting the system into use.

*5.	Where the deployer decides to put the high-risk AI system into use, it shall make the results of the impact assessment available publicly as part of the registration of use pursuant to Article 51(2).*

*6.	Where the deployer is already required to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the impact assessment outlined in paragraph 1 shall be conducted in conjunction to the data protection impact assessment and be published as an addendum.*

*7.	Deployers shall take into account the information provided under Article 13 to comply with their obligations under paragraph 1.*

*8.	Where the deployer finds that the use of a high-risk AI system poses a particular risk to a person or group identified pursuant to Article 29(1 a), it shall notify established representatives or interest groups that act on behalf of those persons or groups before putting the system into use, allow for their response and take it into account for the purpose of the impact assessment.*

Or. en

Amendment 718
Karen Melchior, Yana Toom

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29a
	Recourse for parties affected by decisions of high-risk Artificial Intelligence systems
	1. Where the decision of a high-risk Artificial Intelligence system directly

affects a natural person, that person is entitled to an explanation of the decision, including but not limited to:

(a)   The inputs taken into account by the Artificial Intelligence solution in decision-making.

(b)   Where feasible, the inputs that had the strongest influence on the decision.

2.   Where the decision of a high-risk Artificial Intelligence system directly affects a natural persons economic or social prospects (for instance, job or educational opportunities, access to benefits, public services or credit), and without prejudice to existing sectoral legislation, that person may request that the decision be re-evaluated by a human being. This re-evaluation must take place within reasonable time following the request.

Or. en

Justification

This addition expands Citizens' right to recourse and information when affected by high-risk Artificial Intelligence Systems. It aims to build trust among Citizens.

**Amendment 719
Kosma Złotowski**

**Proposal for a regulation
Article 33 – paragraph 2 a (new)**

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

Or. en

Amendment 720
Kosma Złotowski

Proposal for a regulation
Article 33 – paragraph 6

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

Or. en

Amendment 721
Sergey Lagodinsky

Proposal for a regulation
Article 37 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall*, where necessary,* investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid	1. The Commission shall investigate all cases where there are reasons to doubt whether a notified body complies with the requirements laid down in Article 33.

down in Article 33.

Or. en

Amendment 722
Sergey Lagodinsky

Proposal for a regulation
Article 37 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if *necessary*. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).	4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements laid down in Article 33, it shall adopt a reasoned decision requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if *applicable*. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

Amendment 723
Kosma Złotowski

Proposal for a regulation
Article 41

Text proposed by the Commission	*Amendment*
Article 41	*deleted*
Common specifications	
1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt	

common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

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

3.   High-risk AI systems which are in conformity with the common specifications referred to in paragraph 1 shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.

4.   Where providers do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that are at least equivalent thereto.

Or. en

Amendment 724
Emmanuel Maurel

Proposal for a regulation
Article 41 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.	2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law. *It shall also consult the European Artificial Intelligence Board.*

Or. fr

Amendment 725
Sergey Lagodinsky

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 Annex III, the provider shall *carry out an ex-ante third-party conformity assessment*

Or. en

Amendment 726
Emmanuel Maurel

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. fr

Amendment 727

Emmanuel Maurel

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. fr

Amendment 728
Sergey Lagodinsky

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 729
Sergey Lagodinsky

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

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

Or. en

EN

Amendment 730
Emmanuel Maurel

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

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

Or. fr

Amendment 731
Sergey Lagodinsky

Proposal for a regulation
Article 43 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.	*following* the conformity assessment procedure set out in Annex VII.

Or. en

Justification

(continuation of paragraph 1)

Amendment 732
Sergey Lagodinsky

EN

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 733
Emmanuel Maurel

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, providers shall follow the conformity assessment procedure the conformity assessment procedure based on *assessment of the quality management system and assessment of the technical documentation, with* the involvement of a notified body*, referred to in Annex VII*. 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.

EN

Amendment 734
Sergey Lagodinsky

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 735
Emmanuel Maurel

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	*deleted*

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

Or. fr

Amendment 736
Sergey Lagodinsky

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

Amendment 737
Emmanuel Maurel

Proposal for a regulation
Article 47 – paragraph 2

Text proposed by the Commission	*Amendment*

2.   The authorisation referred to in paragraph 1 shall be issued only if the market surveillance authority concludes that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraph 1.

2.   The authorisation referred to in paragraph 1 shall be issued only if the market surveillance authority concludes that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The market surveillance authority shall inform the Commission*, the European Data Protection Supervisor, the national data protection authorities as defined by Article 51 of Regulation (EU) 2016/679* and the other Member States of any authorisation issued pursuant to paragraph 1.

Or. fr

Amendment 738
Emmanuel Maurel

Proposal for a regulation
Article 47 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.	3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission*, by the European Data Protection Supervisor or by a national data protection authority as defined by Article 51 of Regulation (EU) 2016/679* in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.

Or. fr

Amendment 739
Emmanuel Maurel

Proposal for a regulation
Article 50 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The provider shall, for *a* period *ending 10 years* after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:	The provider shall, for *an unlimited* period after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:

Or. fr

Amendment 740
Emmanuel Maurel

Proposal for a regulation
Title IV

Text proposed by the Commission	*Amendment*
TRANSPARENCY OBLIGATIONS FOR *CERTAIN* AI SYSTEMS	TRANSPARENCY OBLIGATIONS FOR AI SYSTEMS

Or. fr

Amendment 741
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Title IV

Text proposed by the Commission	*Amendment*
TRANSPARENCY OBLIGATIONS *FOR CERTAIN AI SYSTEMS*	TRANSPARENCY OBLIGATIONS

Or. en

Amendment 742
Sergey Lagodinsky

Proposal for a regulation
Title IV

Text proposed by the Commission	*Amendment*

TRANSPARENCY OBLIGATIONS *FOR CERTAIN AI SYSTEMS*	TRANSPARENCY OBLIGATIONS

Or. en

Amendment 743
Emmanuel Maurel

Proposal for a regulation
Article 52 – title

Text proposed by the Commission	*Amendment*

Transparency obligations for *certain* AI systems	Transparency obligations for *all* AI systems

Or. fr

Amendment 744
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 52 – title

Text proposed by the Commission	*Amendment*

Transparency obligations *for certain AI systems*	Transparency obligations

Or. en

Amendment 745
Emmanuel Maurel

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	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.*

persons are designed and developed in such a way that natural persons*, especially those who are least familiar with digital technologies,* are informed that they are interacting with an AI system.

Or. fr

Amendment 746
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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. ***Developers and deployers*** shall ensure that AI systems ***used*** to interact with natural persons are designed and developed in such a way that natural persons are informed*, in a timely, clear and intelligible manner* that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use*. This information shall also include, as appropriate, the functions that are AI enabled, and the rights and processes to allow natural persons to appeal against the application of such AI systems to them*. This obligation shall not apply to AI systems 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

EN

Committee on Legal Affairs

2021/0106(COD)

24.3.2022

AMENDMENTS
747 - 965

Draft opinion
Axel Voss
(PE719.827v01-00)

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))

EN *United in diversity* **EN**

AM_Com_LegOpinion

EN

Amendment 747
Kosma Złotowski

Proposal for a regulation
Article 52 – paragraph 1

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

Or. en

Amendment 748
Brando Benifei

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 timely, clear and intelligible manner* that they are interacting with an AI system. This obligation shall not apply to AI systems authorised by law to detect, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.

Or. en

EN

Amendment 749
Emmanuel Maurel

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.	*deleted*

Or. fr

Amendment 750
Karen Melchior, Svenja Hahn, Yana Toom

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

Justification

The Reliability of emotional recognition systems is already considered to be highly questionable and may infringe on citizens' right to remain silent. At very least, suspects must be informed that they are exposed to such a system.

Amendment 751
Brando Benifei

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 *and obtain their consent prior to exposing them to it*.

Or. en

Amendment 752
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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*, text, scripts* or video content that appreciably resembles existing persons, objects, places*, text, scripts* or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose *in an appropriate clear and visible manner,* that the content has been artificially generated or manipulated*, as well as the name of the natural or legal person that generated or manipulated it*.

Or. en

Amendment 753
Brando Benifei

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

Text proposed by the Commission	*Amendment*
3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall *disclose* that the content has been artificially generated or manipulated.	3. Users of an AI system that generates or manipulates *text, scripts,* 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 *label the content in a way that informs* that the content *is inauthentic and untruthful,* has been artificially generated or manipulated*, and that is clearly visible for the person exposed to it* .

Or. en

Justification

Wording in line with the EP position on the Digital Services Act

Amendment 754
Kosma Złotowski

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

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

Or. en

Amendment 755
Emmanuel Maurel

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. fr

Amendment 756
Brando Benifei

Proposal for a regulation
Article 52 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.	*deleted*

Or. en

EN

Amendment 757
Karen Melchior, Svenja Hahn, Yana Toom

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 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

Justification

Deep fakes or similar techniques could be abused by law enforcement in order to manipulate suspects into false confessions. Such practices should not be encouraged.

Amendment 758
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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.

Amendment 759
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 52 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The information referred to in paragraph 1 to 3 shall be provided to the natural persons in a timely, clear and visible manner, at the latest at the time of the first interaction or exposure. Such information shall be made accessible when the exposed natural person is a person with disabilities, a child or from a vulnerable group. It shall be complete, where possible, with intervention or flagging procedures for the exposed natural person taking into account the generally acknowledged state of the art and relevant harmonised standards and common specifications.

Or. en

Amendment 760
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 52 – paragraph 3 – subparagraph 1 b (new)

Text proposed by the Commission	*Amendment*
	Developers of AI systems with general purposes that are not listed as high-risk in Annex III shall provide relevant information allowing deployers and users to comply with the requirements and obligations set out in Title III of this Regulation. Such systems shall be registered in the EU database set out in Article 60.

EN

Amendment 761
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 52 – paragraph 3 – subparagraph 1 c (new)

Text proposed by the Commission	*Amendment*
	In order to comply with the obligations established in this Article, developers and deployers shall ensure a sufficient level of AI literacy in line with New Article 6.

Or. en

Amendment 762
Jiří Pospíšil

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

Text proposed by the Commission	*Amendment*
	3a. The information referred to in paragraphs1 to 3 shall be provided to natural persons in a clear and easily distinguishable manner at the latest at the time of the first interaction or exposure. The mechanism shall, where relevant and appropriate, be completed with intervention or flagging procedures for the exposed natural person.

Or. en

Amendment 763
Kosma Złotowski

Proposal for a regulation
Article 52 a (new)

| *Text proposed by the Commission* | *Amendment* |

Article 52 a

General purpose AI systems

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

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

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

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

Or. en

Amendment 764
Emmanuel Maurel

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	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

EN

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

development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to *identifying risks to health and safety and fundamental rights, testing mitigation measures for identified risks and demonstrating prevention of these risks in order to ensure* compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.

Or. fr

Amendment 765
Sergey Lagodinsky

Proposal for a regulation
Article 53 – paragraph 1

Text proposed by the Commission	*Amendment*
1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.	1. AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems 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 766
Kosma Złotowski

Proposal for a regulation
Article 53 – paragraph 1

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

Or. en

Amendment 767
Emmanuel Maurel

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 *rectification* and, failing that, in the suspension of the development and testing process until such *rectification* takes place.

Amendment 768
Emmanuel Maurel

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*, in particular with the European Data Protection Supervisor*. 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. fr

Amendment 769
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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	5. Member States' competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the European *Agency for Data and* Artificial Intelligence. They shall submit annual reports to the *Agency* 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.

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 770
Kosma Złotowski

Proposal for a regulation
Article 53 – paragraph 5

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

Or. en

Amendment 771
Emmanuel Maurel

Proposal for a regulation
Article 53 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. When the sandboxes use the data of natural or legal persons, or when the AI system put in place is used to provide persons with results, the latter's consent

must be obtained in advance. The body or company participating in the regulatory sandbox must justify to the final beneficiaries the reasons for its approach. Those persons may refuse to participate.

Or. fr

Amendment 772
Emmanuel Maurel

Proposal for a regulation
Article 54

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

Or. fr

Amendment 773
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

Proposal for a regulation
Article 55 – title

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

Or. en

Amendment 774
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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	(a) provide *SMEs* and start-ups with priority access to the AI regulatory

regulatory sandboxes to the extent that they fulfil the eligibility conditions;

sandboxes to the extent that they fulfil the eligibility conditions;

Or. en

Amendment 775
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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 *SMEs and start-ups*;

Or. en

Amendment 776
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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, start-ups* and other innovators to provide guidance and respond to queries about the implementation of this Regulation.

Or. en

Amendment 777
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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

Text proposed by the Commission	*Amendment*
	(ca) support SME's increased participation in the standardisation development process;

Or. en

Amendment 778
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

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 *SMEs and start-ups* shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.

Or. en

Amendment 779
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Title VI – Chapter 1 – title

Text proposed by the Commission	*Amendment*
1 European Artificial Intelligence *Board*	1 European *Agency for Data and* Artificial Intelligence *('EADA')*

Or. en

Amendment 780
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 56 – title

Text proposed by the Commission	*Amendment*
Establishment of the European Artificial Intelligence ***Board***	European ***Agency for Data and*** Artificial Intelligence ***('EADA')***

Or. en

Amendment 781
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A *'*European Artificial Intelligence ***Board' (the 'Board***') is established.	1. A European ***Agency for Data and*** Artificial Intelligence ***(the 'Agency***') is established ***to promote a trustworthy, effective and competitive internal market for the data and artificial intelligence sectors***.

Or. en

Amendment 782
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 56 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The ***Board*** shall provide advice and assistance to the Commission in order to:	2. The ***Agency*** shall provide advice and assistance to the Commission ***and the Member States, when implementing Union law related to data and artificial intelligence. It shall cooperate with the developers and deployers of AI systems,*** in order to:

Or. en

EN

Amendment 783
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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* the effective cooperation of the national supervisory authorities and the Commission;

Or. en

Amendment 784
Emmanuel Maurel

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) carry out annual reviews and analyses of the complaints sent to and findings made by the national competent authorities, of the reports of serious incidents and malfunctioning referred to in Article 62, and of new registrations in the EU database referred to in Article 60 in order to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens that are not adequately addressed by this Regulation; carry out biannual analyses of the future and prospective analyses in order to extrapolate the possible impact of these trends and emerging issues on the Union; and publish annual recommendations to the Commission, including, but not limited to, recommendations on the categorisation of prohibited practices, high-risk systems, and codes of conduct for AI systems that are not classified as high-risk.

Amendment 785
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 786
Sergey Lagodinsky

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) propose amendments to Annexes I and III.

Or. en

Amendment 787
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 56 – paragraph 2 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) issue recommendations and carry out assessments of the compliance by developers and deployers and the enforcement by national supervisory

authorities of Articles 70 to 74.

Or. en

Amendment 788
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 56 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Agency shall act as a reference point for advice and expertise for Union institutions, bodies, offices and agencies as well as for other relevant stakeholders on matters related to data and artificial intelligence.

Or. en

Amendment 789
Emmanuel Maurel

Proposal for a regulation
Article 56 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Board shall have a sufficient number of competent personnel at its disposal to assist it in the proper performance of its tasks.

Or. fr

Amendment 790
Emmanuel Maurel

Proposal for a regulation
Article 56 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Board shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. It shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality in all its activities.

Or. fr

Amendment 791
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 56 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Agency shall act as a contact point for persons or groups of persons affected by AI systems when there has been no national enforcement of their rights under Article 70a to 74 or when the AI system affecting or harming them is deployed and used in more than one Member State

Or. en

Amendment 792
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 57 – title

Text proposed by the Commission	*Amendment*
Structure of the ***Board***	***Mandate and*** structure of the ***Agency***

Or. en

Amendment 793
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 57 – paragraph -1 (new)

Text proposed by the Commission	*Amendment*
	-1. The Agency shall have a Chair elected by qualified majority among the members of its board. It shall carry out its tasks independently, impartially, transparently and in a timely manner. It shall have a strong mandate, a secretariat as well as sufficient resources and skilled personnel at its disposal for the proper performance of its tasks. The mandate of the Agency shall contain the operational aspects related to the execution of the Agency's tasks as listed in Article 58.

Or. en

Amendment 794
Emmanuel Maurel

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, *representatives of the ethics committees of the Member States or, for those countries that have no such committees, ethics academics, researchers or experts,* and the European Data Protection Supervisor. Other national authorities *shall* be invited to the meetings, where the issues discussed are of relevance for them. *The Board shall cooperate closely with the national data protection authorities as defined by Article 51 of Regulation (EU) 2016/679.*

Amendment 795
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 Agency shall establish a board.*** 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, ***representatives of the European Commission as well as, high level representatives from*** the European Data Protection Supervisor***, the EU Agency for Fundamental Rights and the EU Agency for Cybersecurity***. Other national authorities***, as well as other Union bodies, offices, agencies and advisory groups shall*** be invited to the meetings, where the issues discussed are of relevance for them.

Or. en

Amendment 796
Sergey Lagodinsky

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. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them. ***The Board composition shall be gender balanced.***

Or. en

Amendment 797
Kosma Złotowski

Proposal for a regulation
Article 57 – paragraph 1

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

Or. en

Amendment 798
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 57 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Board shall adopt its rules of procedure by a simple majority of its members, **following the consent** of the **Commission. The** rules of procedure **shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58.** The Board **may establish sub-groups as appropriate for the purpose of examining specific questions**.	2. The **Agency's** board shall adopt its rules of procedure**, namely with regard to the election of its Chair,** by a simple majority of its members, **with the assistance** of the **Agency's secretariat. The Agency's secretariat shall convene the meetings and prepare the agenda in accordance with the task of the Agency's board pursuant with its** rules of procedure**. The Agency's secretariat will provide administrative and analytical support for the activities of** the board **pursuant to this Regulation**.

Or. en

Amendment 799
Emmanuel Maurel

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Board shall be chaired by the Commission. The Commission shall *convene the meetings and* prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.	3. The Board shall be chaired by the Commission.
	The Board may be convened by the Commission, on its own initiative or at the request of a Member State, a national authority responsible for the protection of fundamental rights or personal data or a national ethics committee.
	The Commission shall prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. fr

Amendment 800
Kosma Złotowski

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Board shall be *chaired* by the Commission. The Commission shall convene the meetings and prepare the	3. The Board shall be *co-chaired* by the Commission *and representative chosen from among the delegates of the*

agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Member States. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Or. en

Amendment 801
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***Board*** shall ***be chaired by the Commission. The Commission shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The Commission shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation***.	3. The ***Agency*** shall ***establish a Permanent Stakeholders' Group composed of experts representing the relevant stakeholders, such as representatives of developers, deployers and users of AI systems, including SMEs and start-ups, consumer groups, trade unions, fundamental rights organisations and academic experts***.

Or. en

Amendment 802
Sergey Lagodinsky

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	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.

between the Board and other Union bodies, offices, agencies and advisory groups. *The Board shall ensure a balanced representation of stakeholders from academia, research, and industry when it invites external experts and observers, and actively stimulate participation from underrepresented categories.*

Or. en

Amendment 803
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *Agency shall also inform* interested third parties *and citizens on* its activities to an appropriate extent.

Or. en

Amendment 804
Emmanuel Maurel

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	4. The Committee may invite external experts and observers. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and *specialised* groups. *The composition of the specialised body*

EN

exchanges between the Board and other Union bodies, offices, agencies and *advisory* groups.

shall guarantee fair representation of consumer organisations, civil society organisations and academics specialising in AI and in ethics. Its meetings and their minutes shall be published online.

Or. fr

Amendment 805
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – title

Text proposed by the Commission	*Amendment*
Tasks of the **Board**	Tasks of the **Agency**

Or. en

Amendment 806
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
When providing advice and assistance to the Commission *in the context of Article 56(2), the Board* shall *in particular*:	When providing advice and assistance to the Commission *, the Member States and in cooperation with the developers, deployers and users of AI systems with regard to the application of this Regulation , the Agency* shall:

Or. en

Amendment 807
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) promote and support the cooperation among national supervisory authorities and the Commission, and ensure the Union safeguard procedure referred to Article 66;

Or. en

Amendment 808
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 809
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission	*Amendment*
	(iia) on the provisions related to post market monitoring as referred to in Article 61,

Or. en

Amendment 810
Emmanuel Maurel

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) on the adaptation of this Regulation to technological, social and scientific developments, and on the need to revise this Regulation.

Or. fr

Amendment 811
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) on the need for the amendment of each of the Annexes as referred to in Article 73,

Or. en

Amendment 812
Sergey Lagodinsky

Proposal for a regulation
Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) on amendments to the Annexes I and III

Or. en

Amendment 813
Emmanuel Maurel

Proposal for a regulation
Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) be able to ask the Commission to revise Annex III to this Regulation on high-risk AI systems. In this case, the Board shall draw up precise recommendations for the revision. The Commission shall take these recommendations into consideration and shall publish a comparative report allowing its follow-up to the recommendations to be assessed and containing specific justifications.

Or. fr

Amendment 814
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) to establish and maintain the EU database for stand-alone high risk AI systems, referred to in Article 60;

Or. en

Amendment 815
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) to carry out annual reviews and analysis of the complaints sent to and the findings made by the national competent authorities of the serious incidents report referred to in Article 62;

Amendment 816
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c c (new)

Text proposed by the Commission	*Amendment*
	(cc) to act as the market surveillance authority where Union institutions, agencies and bodies fall within the scope of this Regulation, as referred to in paragraph 6 of Article 63 and Article 72;

Or. en

Amendment 817
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission	*Amendment*
	(cd) to provide guidance material to developers, deployers and users regarding the compliance with the requirements set out in this Regulation. In particular, it shall issue guidelines:
	i) for the trustworthy AI technical assessment referred to in paragraph 6 of new Article 4a,
	ii) for the preliminary risk self-assessment referred to in new Article 5a;
	iii) for the methods for performing the conformity assessment based on internal control referred to Article 43;
	iv) to facilitate compliance with the reporting of serious incidents and of malfunctioning referred to in Article 62;
	v) to facilitate the drawing up of the

mandatory Codes of Conduct referred to in Article 69;

vi) on any other concrete procedures to be performed by developers, deployers and users when complying with this Regulation, in particular those regarding the documentation to be delivered to notified bodies and methods to provide authorities with other relevant information.

Or. en

Amendment 818
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission	*Amendment*
	(ce) to provide specific guidance to help and alleviate the burden to SMEs, start-ups or small-scale operators, regarding the compliance of the obligations set out in this Regulation;

Or. en

Amendment 819
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission	*Amendment*
	(cf) to raise awareness and provide guidance material to developers, deployers regarding the compliance with the requirement to put in place tools and measures to ensure a sufficient level of AI literacy in line with new Article 6.

Amendment 820
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission	*Amendment*
	(cg) to contribute to the Union efforts to cooperate with third countries and international organisations in view of promoting a common global approach towards trustworthy AI;

Or. en

Amendment 821
Emmanuel Maurel

Proposal for a regulation
Article 59 – paragraph 1

Text proposed by the Commission	*Amendment*
1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their activities and tasks.	1. National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their activities and tasks. *They shall ensure a high level of harmonisation in the application of this Regulation. They shall put in place all of the resources needed to achieve this and shall strive for uniform application of this Regulation in the Union.*

Or. fr

Amendment 822
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 59 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall inform the Commission of their designation or designations and, where applicable, the reasons for designating more than one authority.	3. Member States shall inform the Commission **and the Agency** of their designation or designations and, where applicable, the reasons for designating more than one authority.

Or. en

Amendment 823
Emmanuel Maurel

Proposal for a regulation
Article 59 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission shall ensure that this Regulation is applied uniformly in the Union. The Member States and all interested parties may notify the Commission of any cases where the national authorities are not fulfilling their obligations. With the support of the European Artificial Intelligence Board, the Commission may carry out an investigation and, if necessary, ask the national authorities to adapt their practices in order to ensure application of this Regulation. The national authorities shall take due account of the Commission's recommendations and adapt their practices accordingly.

Or. fr

Amendment 824
Kosma Złotowski

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

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

Or. en

Amendment 825
Kosma Złotowski

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

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

Or. en

Amendment 826
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 59 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall report to the Commission on an annual basis on the	5. Member States shall report to the Commission on an annual basis on the

status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the **Board** for discussion and possible recommendations.

status of the financial and human resources of the national competent authorities with an assessment of their adequacy. The Commission shall transmit that information to the **Agency** for discussion and possible recommendations.

Or. en

Amendment 827
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 59 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The **Commission** shall facilitate the exchange of experience between national competent authorities.	6. The **Agency** shall facilitate the exchange of experience between national competent authorities.

Or. en

Amendment 828
Kosma Złotowski

Proposal for a regulation
Article 59 – paragraph 7

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

Member State should be contactable through electronic communications means.

Or. en

Amendment 829
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

Proposal for a regulation
Article 59 – paragraph 7

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

Or. en

Amendment 830
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 59 – paragraph 8

Text proposed by the Commission	*Amendment*
8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the *European Data Protection Supervisor* shall act as the competent authority for their supervision.	8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the *Agency* shall act as the competent authority for their supervision.

Or. en

EN

Amendment 831
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *Agency* 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*, as well as the information referred to in new paragraph 3x new of Article 52*.

Or. en

Amendment 832
Emmanuel Maurel

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 *regularly* 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.

Or. fr

Amendment 833
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation

EN

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. The *Agency* shall provide them with technical and administrative support.

Or. en

Amendment 834
Emmanuel Maurel

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 *easily* accessible to the public *in the official languages of the Union*.

Or. fr

Amendment 835
Emmanuel Maurel

Proposal for a regulation
Article 60 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Users must register deployment of high-risk AI systems in the EU database before putting them into service. Users must include information in the database, notably the identity of the provider and the user, the context of the objective and the deployment, the designation of the persons affected and the results of the impact assessment.

Amendment 836
Kosma Złotowski

Proposal for a regulation
Article 60 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The EU database shall not contain any confidential business information or trade secrets of a natural or legal person, including source code.

Or. en

Amendment 837
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 *Agency* shall be the controller of the EU database. It shall also ensure to providers adequate technical and administrative support.

Or. en

Amendment 838
Kosma Złotowski

Proposal for a regulation
Article 60 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Any information and documentation obtained by the Commission and Member States pursuant to the provisions of this Article shall be

treated in compliance with the confidentiality obligations set out in Article 70.

Or. en

Amendment 839
Emmanuel Maurel

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*, the use* and the risks of the high-risk AI system.

Or. fr

Amendment 840
Emmanuel Maurel

Proposal for a regulation
Article 61 a (new)

Text proposed by the Commission	*Amendment*
	Article 61a.
	Establishment by providers of a reporting system
	AI system providers shall make available to users, final beneficiaries, national authorities and all interested parties a reporting system that can be used to flag up any problem involving the functioning of the AI system, or its compliance with this Regulation and Union law or current national law. Providers shall examine these notifications diligently. They shall examine and respond to the notifications

within a reasonable period of time and shall report the problems to the national authorities.

<div align="right">

Or. fr

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Amendment 841
Emmanuel Maurel

Proposal for a regulation
Recital 61 b (new)

Text proposed by the Commission	*Amendment*
	Article 61b.
	Tasks of the public authorities in the monitoring of AI systems
	1. If AI systems are used by public authorities or on their behalf, users shall put in place a monitoring system to detect any problems or shortcomings in the AI system that might result in a violation of fundamental rights, notably the principle of non-discrimination.
	2. Users shall inform the providers of any problem caused by use of the AI system via the reporting system provided for in Article (61).
	3. Users shall put in place all of the necessary measures to detect any harmful effects that using an AI system could have on the right of users to access public services.

<div align="right">

Or. fr

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Amendment 842
Sergey Lagodinsky

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 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 *or* fundamental rights to the market surveillance authorities of the Member States where that incident or breach occurred.

Or. en

Amendment 843
Emmanuel Maurel

Proposal for a regulation
Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Such notification shall be made immediately after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than *15* days after the providers becomes aware of the serious incident or of the malfunctioning.	Such notification shall be made immediately after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than *7* days after the providers becomes aware of the serious incident or of the malfunctioning.

Or. fr

Amendment 844
Sergey Lagodinsky

Proposal for a regulation
Article 62 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Upon receiving a notification related to a breach of obligations under Union law *intended to protect* fundamental rights, the market surveillance authority	2. Upon receiving a notification related to a breach of obligations under Union law *or* fundamental rights, the market surveillance authority shall inform

shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.

the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.

Or. en

Amendment 845
Sergey Lagodinsky

Proposal for a regulation
Article 62 – paragraph 3

Text proposed by the Commission	*Amendment*
3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those that that constitute a breach of obligations under Union law *intended to protect* fundamental rights.	3. For high-risk AI systems referred to in point 5(b) of Annex III which are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU and for high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the notification of serious incidents or malfunctioning shall be limited to those that that constitute a breach of obligations under Union law *or* fundamental rights.

Or. en

Amendment 846
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Where Union institutions, agencies	6. Where Union institutions, agencies

and bodies fall within the scope of this Regulation, the *European Data Protection Supervisor* shall act as their market surveillance authority.

and bodies fall within the scope of this Regulation, the *Agency* shall act as their market surveillance authority.

Or. en

Amendment 847
Kosma Złotowski

Proposal for a regulation
Article 64 – paragraph 1

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

Or. en

Amendment 848
Kosma Złotowski

Proposal for a regulation
Article 64 – paragraph 2

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

Amendment 849
Sergey Lagodinsky

Proposal for a regulation
Article 64 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law *intended to protect* fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.	5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law *or* fundamental rights has occurred, the public authority or body referred to paragraph 3 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

Or. en

Amendment 850
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 65 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.	3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform *the Agency,* the Commission and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.

Or. en

Amendment 851
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 65 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall inform the Commission and the other Member States, without delay, of those measures.	5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market, to withdraw the product from that market or to recall it. That authority shall inform the *Agency, the* Commission and the other Member States, without delay, of those measures.

Or. en

Amendment 852
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 65 – paragraph 6 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) the non-compliance with new Article 4a;

Or. en

Amendment 853
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 65 – paragraph 7

Text proposed by the Commission	*Amendment*

7. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform *the Agency,* the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

Or. en

Amendment 854
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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 a Member State against a measure taken by another Member State, or where the *Agency or the* Commission considers the measure to be contrary to Union law, the *Agency* 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 *Agency* shall decide whether the national measure is justified or not within *6* months from the notification referred to in Article 65(5) and notify such decision to the Member State concerned.

Or. en

Amendment 855
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 66 – paragraph 2

Text proposed by the Commission	*Amendment*
2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the *Commission* accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.	2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market, and shall inform the *Agency* accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

Or. en

Amendment 856
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 67 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.	3. The Member State shall immediately inform *the Agency,* the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Or. en

Amendment 857
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 67 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall address its decision to the Member States.	5. The Commission shall address its decision to the *Agency and the* Member States.

Or. en

Amendment 858
Sergey Lagodinsky

Proposal for a regulation
Article 68 a (new)

Text proposed by the Commission	*Amendment*
	Article 68 a
	Right to lodge a complaint with a supervisory authority
	1. End-users and consumers affected by an AI system shall have the right to lodge a complaint against the providers or deployers of such AI system if they consider that the system in question or the practices in which the provider or user have engaged infringe this Regulation. Such complaint may be lodged with the authority in charge to handle complaints, notably with a market surveillance authority, in the Member State of his or her habitual residence or domicile, place of work or place of the alleged infringement. Such complaint may be lodged through a representative action for the protection of the collective interests of consumers as provided under Directive (EU) 2020/1828
	2. End-users, consumers or their representatives shall have a right to be heard in the complaint handling procedure and in the context of any investigations conducted by the competent authority as a result of their complaint.
	3. Supervisory authorities shall inform end-users, consumers or their

representatives about the progress and outcome of their complaints. In particular, supervisory authorities shall take all the necessary actions to follow up on the complaints they receive and, within three months of the reception of a complaint, give the complainants a preliminary response indicating the measures they intend to take and the next steps in the procedure, if any.

4. The supervisory authority shall take a decision on the complaint, including the possibility of a judicial remedy pursuant to Article 68b, without delay and no later than six months after the date on which the complaint was lodged.

Or. en

(Directive (EU) 2020/1828)

Amendment 859
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 68 a (new)

Text proposed by the Commission	*Amendment*
	Article 68 a
	Reporting of breaches and protection of reporting persons
	Directive (EU) 2019/1937 of the European Parliament and of the Council[1a] shall apply to the reporting of breaches of this Regulation and the protection of persons reporting such breaches.
	_____
	[1a] Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

Amendment 860
Sergey Lagodinsky

Proposal for a regulation
Article 68 b (new)

Text proposed by the Commission	*Amendment*
	Article 68 b
	Right to an effective judicial remedy against a market surveillance authority
	1. Without prejudice to any other administrative or non-judicial remedy, consumers and their representatives shall have the right to an effective judicial remedy against a legally binding decision of a market surveillance authority concerning them.
	2. Without prejudice to any other administrative or non-judicial remedy, consumers shall have the right to a an effective judicial remedy where the market surveillance authority which is competent pursuant to Article 63 does not handle a complaint, does not inform the consumer on the progress or preliminary outcome of the complaint lodged within three months pursuant to Article 68a (3), does not comply with its obligation to reach a final decision on the complaint within six months pursuant to Article 68a (3) or its obligations under Article 65.
	3. Proceedings against a market surveillance authority shall be brought before the courts of the Member State where the authority is established.

Or. en

Amendment 861
Sergey Lagodinsky

Proposal for a regulation
Article 68 c (new)

Text proposed by the Commission	*Amendment*
	Article 68 c
	Remedies
	1. Without prejudice to the right to lodge a complaint with a supervisory authority pursuant to Article 68a and any other remedies available pursuant to applicable EU and Member State law, and-users, consumers and their representatives shall be able to seek judicial and non-judicial remedies against providers or users of AI systems, including repair, replacement, price reduction, contract termination, reimbursement of the price paid or compensation for material and immaterial damages, for breaches of the rights and obligations set out in this Regulation.
	2. Deployers of AI systems which may affect end-users or consumers must provide an effective complaint handling system which enables end-user or consumer complaints to be lodged electronically and free of charge, and ensure that complaints submitted through this system are dealt with in an efficient and expedient manner.
	3. Deployers of AI systems shall ensure that their internal complaint-handling systems are easy to access, user-friendly and enable and facilitate the submission of sufficiently precise and adequately substantiated complaints.

Or. en

Amendment 862
Sergey Lagodinsky

Proposal for a regulation
Article 68 d (new)

Text proposed by the Commission	*Amendment*

Article 68 d

Representation of affected persons

1. Without prejudice to Directive 2020/1828/EC, affected persons shall have the right to mandate a body, organisation or association to exercise the rights referred to in Articles 68a, 68b and 68c on their behalf, provided that the body, organisation or association meets all of the following conditions:

a) operates on a not-for-profit basis;

b) it has been properly constituted in accordance of the law of a Member State;

c) its statutory objectives include a legitimate interesting in ensuring that that this Regulation is complied with.

2. Without prejudice to Directive 2020/1828/EC, the bodies, organisations or associations referred to in paragraph 1 shall have the right to exercise the rights established in Articles 68a, 68b and 68c independently of the mandate of an affected person, if they consider that a provider or user of an AI system has infringed any of the rights or obligations set out in this Regulation.

Or. en

(Directive 2020/1828/EC)

Amendment 863
Emmanuel Maurel

Proposal for a regulation
Title VIII – Chapter 3 a (new)

Text proposed by the Commission	*Amendment*

3a.   DIRECT COMPLAINT PROCEDURE AND REDRESS

MECHANISM

Article 68a Right to lodge a complaint with a supervisory authority

1. Persons shall have the right to not be subject to prohibited AI systems.

2. Persons shall have the right to not be subject to high-risk AI systems that do not meet the requirements for high-risk systems.

3. Persons shall have the right to not be subject to AI systems that pose an unacceptable risk or that do not comply with this Regulation.

4. Without prejudice to any other administrative or judicial remedy, all citizens shall have the right to lodge a complaint with a surveillance authority, particularly in the Member State where they are habitually resident, where they work or where the alleged offence has taken place, if they believe that they have been subject to an AI system that infringes this Regulation.

Persons shall have the right to receive a clear and intelligible explanation, in an accessible format for persons with disabilities, regarding the decisions taken with the help of systems that fall within the scope of AI.

Persons shall have the right to an effective remedy if their rights under this Regulation have been infringed after an AI system has been put into service. This remedy must be accessible to both individuals and groups.

5. The supervisory authority with which the complaint has been lodged shall inform the complainant about the progress and the outcome of the complaint.

Or. fr

EN

Amendment 864
Ibán García Del Blanco, Tiemo Wölken, René Repasi

Proposal for a regulation
Article 69 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission and the Member States shall *encourage and facilitate the* drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the *intended* purpose of the systems.	1. The Commission and the Member States shall *support the mandatory* drawing up of codes of conduct intended *to demonstrate compliance with the ethical principles underpinning trustworthy AI set out in Article 4a and* to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the purpose of the systems.

Or. en

Amendment 865
Brando Benifei

Proposal for a regulation
Article 69 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of *the requirements set out in Title III, Chapter 2* on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.	1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of *articles 10, 13 and 15 of this Regulation* on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

Or. en

Amendment 866
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 69 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***The Commission and the Board shall encourage and facilitate* the drawing up *of* codes of conduct intended to *foster the voluntary application to* AI systems *of requirements related for example to environmental sustainability, accessibility for* persons with *a disability, stakeholders participation in the design and development of the* AI systems *and diversity of* development teams *on the basis of clear objectives and key performance indicators to measure the achievement of those objectives*.**	2. ***In* the drawing up codes of conduct intended to *ensure and demonstrate compliance with the ethical principles underpinning trustworthy AI set out in Article 4a, developers and deployers shall, in particular:***
	(a) consider whether there is a sufficient level of AI literacy among their staff and any other persons dealing with the operation and use of AI systems in order to observe such principles;
	(b) assess to what extent their AI systems may affect vulnerable persons or groups of persons, including children, the elderly, migrants and persons with disabilities or whether any measures could be put in place in order to support such persons or groups of persons;
	(c) pay attention to the way in which the use of their AI systems may have an impact on gender balance and equality;
	(d) have especial regard to whether their AI systems can be used in a way that, directly or indirectly, may residually or significantly reinforce existing biases or inequalities;
	(e) reflect on the need and relevance of having in place diverse development teams in view of securing an inclusive design of

their systems;

(f) give careful consideration to whether their systems can have a negative societal impact, notably concerning political institutions and democratic processes;

(g) evaluate the extent to which the operation of their AI systems would allow them to fully comply with the obligation to provide an explanation laid down in Article New 71 of this Regulation;

(h) take stock of the Union's commitments under the European Green Deal and the European Declaration on Digital Rights and Principles;

(i) state their commitment to privileging, where reasonable and feasible, the common specifications to be drafted by the Commission pursuant to Article 41 rather than their own individual technical solutions.

Or. en

Amendment 867
Sergey Lagodinsky

Proposal for a regulation
Article 69 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.	2. The Commission and the Board shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with a disability, stakeholders participation in the design and development of the AI systems and diversity **and gender-balance** of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.

Amendment 868
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 69 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Codes of conduct may be drawn up by individual *providers* of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the *intended* purpose of the relevant systems.	3. Codes of conduct may be drawn up by individual *developers and deployers* of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations*, in particular trade unions, and consumer organisations*. Codes of conduct may cover one or more AI systems taking into account the similarity of the purpose of the relevant systems.

Or. en

Amendment 869
Sergey Lagodinsky

Proposal for a regulation
Article 69 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.	3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders*, including scientific researchers,* and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

Or. en

Amendment 870
Emmanuel Maurel

Proposal for a regulation
Article 69 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Codes of conduct *may* be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.	3. Codes of conduct *shall* be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders and their representative organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

Or. fr

Amendment 871
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 69 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Developers and deployers shall designate at least one natural person that is responsible for the internal monitoring of the drawing up of their code of conduct and for verifying compliance with that code of conduct in the course of their activities. That person shall serve as a contact point for users, stakeholders, national competent authorities, the Commission and the European Agency for Data and AI on all matters concerning the code of conduct.

Or. en

EN

Amendment 872
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission and the **Board** shall take into account the specific interests and needs of the small-scale providers and start-ups when **encouraging and facilitating** the drawing up of codes of conduct.	4. The Commission and the **European Agency for Data and AI** shall take into account the specific interests and needs of the small-scale providers and start-ups when **supporting** the drawing up of codes of conduct.

Or. en

Amendment 873
Emmanuel Maurel

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission and the Board **shall** take into account the specific interests and needs of the small-scale providers and start-ups when encouraging and facilitating the drawing up of codes of conduct.	4. The Commission and the Board **may** take into account the specific interests and needs of the small-scale providers and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. fr

Amendment 874
Sergey Lagodinsky

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission and the Board shall take into account the specific interests and needs of the small-scale providers and	4. The Commission and the Board shall take into account the specific interests and needs of the small-scale providers**,**

start-ups when encouraging and facilitating the drawing up of codes of conduct.

SMEs and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. en

Amendment 875
Svenja Hahn, Ilhan Kyuchyuk, Nicola Beer

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission and the Board shall take into account the specific interests and needs of *the small-scale providers* and start-ups when encouraging and facilitating the drawing up of codes of conduct.	4. The Commission and the Board shall take into account the specific interests and needs of *SMEs* and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Or. en

Amendment 876
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 69 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. In order to comply with the obligations established in this Article, developers and deployers shall ensure a sufficient level of AI literacy in line with New Article 6.

Or. en

Amendment 877
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Title X

Text proposed by the Commission	*Amendment*
CONFIDENTIALITY AND PENALTIES	CONFIDENTIALITY, ***REMEDIES*** AND PENALTIES

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

Amendment 878
Kosma Złotowski

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

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

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

Amendment 879
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
	***1a.** Where the activities of national competent authorities, market surveillance authorities and bodies notified under the provisions of this Article infringe intellectual property rights, Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of intellectual property rights in full application of Directive 2004/48/EC on*

the enforcement of intellectual property rights.

Or. en

Amendment 880
Kosma Złotowski

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

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

Or. en

Amendment 881
Emmanuel Maurel

Proposal for a regulation
Article 70 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission and Member States may exchange, where	*deleted*

necessary, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Or. fr

Amendment 882
Tiemo Wölken

Proposal for a regulation
Article 70 a (new)

Text proposed by the Commission	*Amendment*
	Article 70 a
	Right to an explanation
	1. Any persons or groups of persons subject to a decision taken by a deployer or user on the basis of output from an AI system which produces legal effects, or which significantly affects them, shall have the right to receive from the deployer, upon request and, where concerning AI systems other than high-risk that are not subject to the requirements of Article 13 of this Regulation, at the time when the decision is communicated, a clear and meaningful explanation of:
	(a) the logic involved, the main parameters of decision-making and their relative weight;
	(b) the input data relating to the affected person or groups of persons and each of the main parameters on which the decision was made, including an easily understandable description of inferences drawn from other data if it is the inference that relates to a main parameter.
	2. Paragraph 1 shall not apply to the use

of AI systems:

(a) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law, which lays down other appropriate safeguards for the affected person or groups of persons' rights and freedoms and legitimate interests; or

(b) where the affected person has given free, explicit, specific and informed consent not to receive an explanation.

Or. en

Amendment 883
Ibán García Del Blanco, René Repasi

Proposal for a regulation
Article 70 a (new)

Text proposed by the Commission	*Amendment*
	Article 70 a
	Right to an explanation
	1. Any persons or groups of persons subject to a decision taken by a deployer or user on the basis of output from an AI system which produces legal effects, or which significantly affects them, shall have the right to receive from the deployer, upon request and, where concerning AI systems other than high-risk that are not subject to the requirements of Article 13 of this Regulation, at the time when the decision is communicated, a clear and meaningful explanation of:
	(a) the logic involved, the main parameters of decision-making and their relative weight;
	(b) the input data relating to the affected person or groups of persons and each of the main parameters on which the decision was made, including an easily

understandable description of inferences drawn from other data if it is the inference that relates to a main parameter.

2. Paragraph 1 shall not apply to the use of AI systems:

(a) that are authorised by law to detect, prevent, investigate and prosecute criminal offences or other unlawful behaviour;

(b) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law, which lays down other appropriate safeguards for the affected person or groups of persons' rights and freedoms and legitimate interests; or

(c) where the affected person has given free, explicit, specific and informed consent not to receive an explanation.

Or. en

Amendment 884
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 70 b (new)

Text proposed by the Commission	*Amendment*
	Article 70 b
	Right to lodge a complaint
	1. Every person or groups of persons harmed by AI systems shall have the right to lodge a complaint with a supervisory authority , in particular in the Member State of his or her habitual residence, place of work or place of the alleged harm if the person or groups of persons considers that the development, deployment or use of one or more AI systems infringes this Regulation.

2. The person or groups of persons shall have a right to be heard in the complaint handling procedure and in the context of any investigations conducted by the supervisory authority as a result of their complaint.

3. The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint. In particular, supervisory authorities shall take all the necessary actions to follow up on the complaints they receive and, within three months of the reception of a complaint, give the complainant a preliminary response indicating the measures it intends to take and next steps in the procedure, if any.

4. The supervisory authority shall take a decision on the complaint, including the possibility of a judicial remedy pursuant to new Article 73, without delay and no later than six months after the date on which the complaint was lodged.

Or. en

Amendment 885
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 70 c (new)

Text proposed by the Commission	*Amendment*
	Article 70 c
	Right to an effective judicial remedy against a 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 supervisory authority concerning them.

2. Without prejudice to any other administrative or non-judicial remedy, each person or groups of persons harmed by AI systems shall have the right to an effective judicial remedy where the supervisory authority does not inform them on the progress or preliminary outcome of the complaint lodged within three months pursuant to paragraph 3 of Article new 72, does not comply with its obligation to reach a final decision on the complaint within six months pursuant to paragraph 4 of Article new 72 or with its obligations under Article 65.

3. Proceedings against a supervisory authority shall be brought before the courts of the Member State where the national competent authority or notified body is established.

Or. en

Amendment 886
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 70 d (new)

Text proposed by the Commission	*Amendment*
	Article 70 d
	Representation of affected persons or groups of persons
	1. Without prejudice to Directive 2020/1828/EC, the person or groups of persons harmed by AI systems shall have the right to mandate a not-for-profit body, organisation or association which has been properly constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest, and is active in the field of the protection of rights and freedoms impacted by AI to lodge the complaint on his, her or their behalf, to exercise the rights referred to in Articles New 71, New

72 and New 73 on his or her behalf.

2. Without prejudice to Directive 2020/1828/EC, the body, organisation or association referred to in paragraph 1 shall have the right to exercise the rights established in Articles New 72 and New 73 independently of a mandate by a person or groups of person if it considers that a developer or a deployer has infringed any of the rights or obligations set out in this Regulation.

Or. en

Amendment 887
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 70 e (new)

Text proposed by the Commission	*Amendment*
	Article 70 e
	Representative actions
	1. The following is added to Annex I of Directive 2020/1828/EC on Representative actions for the protection of the collective interests of consumers:
	"Regulation xxxx/xxxx of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts".

Or. en

Amendment 888
Kosma Złotowski

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

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

Or. en

Amendment 889
Emmanuel Maurel

Proposal for a regulation
Article 71 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The following infringements shall be subject to administrative fines of up to *30 000 000* EUR or, if the offender is company, up to *6* % of its total worldwide annual turnover for the preceding financial year, whichever is higher:	3. The following infringements shall be subject to administrative fines of up to *50 000 000* EUR or, if the offender is company, up to *10* % of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Or. fr

Amendment 890
Kosma Złotowski

Proposal for a regulation
Article 71 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The following infringements shall be subject to administrative fines of up to *30 000 000* EUR or, if the offender is company, up to *6* % of its total worldwide annual turnover for the preceding financial year, whichever is higher*:*	3. The following infringements shall be subject to administrative fines of up to *15 000 000* EUR or, if the offender is company, up to *3* % of its total worldwide annual turnover for the preceding financial year, whichever is higher*.*

Or. en

Amendment 891
Kosma Złotowski

Proposal for a regulation
Article 71 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to *20 000 000* EUR or, if the offender is a company, up to *4* % of its total worldwide annual turnover for the preceding financial year, whichever is higher.	4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to *10 000 000* EUR or, if the offender is a company, up to *2* % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 892
Emmanuel Maurel

Proposal for a regulation
Article 71 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to *20 000 000* EUR or, if the offender is a company, up to *4* % of its total worldwide annual turnover for the preceding financial year, whichever is higher.	4. The 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 *40 000 000* EUR or, if the offender is a company, up to *8* % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. fr

Amendment 893
Emmanuel Maurel

EN

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 *20 000 000* EUR or, if the offender is a company, up to *4* % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. fr

Amendment 894
Kosma Złotowski

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 *5 000 000* EUR or, if the offender is a company, up to *1* % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

Amendment 895
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 72 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*

1. The *European Data Protection Supervisor* may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

1. The *Agency* may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Or. en

Amendment 896
Kosma Złotowski

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

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

Or. en

Amendment 897
Kosma Złotowski

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

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

Or. en

Amendment 898
Kosma Złotowski

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

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

Or. en

Amendment 899
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

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

Text proposed by the Commission	*Amendment*
(b) the cooperation with the *European Data Protection Supervisor* in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the *European Data Protection Supervisor* against the Union institution or agency or body concerned with regard to the same subject matter;	(b) the cooperation with the *Agency* in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the *Agency* against the Union institution or agency or body concerned with regard to the same subject matter;

Or. en

Amendment 900
Kosma Złotowski

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

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

EN

adverse effects of the infringement;

Or. en

Amendment 901
Kosma Złotowski

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

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

Or. en

Amendment 902
Kosma Złotowski

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

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

Or. en

Amendment 903
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 72 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Before taking decisions pursuant to	4. Before taking decisions pursuant to

EN

this Article, the *European Data Protection Supervisor* shall give the Union institution, agency or body which is the subject of the proceedings conducted by the *European Data Protection Supervisor* the opportunity of being heard on the matter regarding the possible infringement. The European *Data Protection Supervisor* shall base *his or her* decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.

this Article, the *Agency* shall give the Union institution, agency or body which is the subject of the proceedings conducted by the *Agency* the opportunity of being heard on the matter regarding the possible infringement. The European *Agency* shall base *its* decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.

Or. en

Amendment 904
Ibán García Del Blanco, Tiemo Wölken, René Repasi, Maria-Manuel Leitão-Marques

Proposal for a regulation
Article 72 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the *European Data Protection Supervisor's* file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.	5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the *Agency's* file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.

Or. en

Amendment 905
Karen Melchior, Yana Toom

Proposal for a regulation
Article 73 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3),	2. The delegation of power referred to in Article 4*, Article 5a(1)*, Article 7(1),

Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Or. en

Justification

This amendment gives the Commission the possibility to amend by way of delegated act the annex listing additional banned practices. This future-proofs the legislation.

Amendment 906
Karen Melchior, Yana Toom

Proposal for a regulation
Article 73 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Article 4*, Article 5a(1)*, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Justification

This amendment gives the Commission the possibility to amend by way of delegated act the annex listing additional banned practices. This future-proofs the legislation.

Amendment 907
Sergey Lagodinsky

Proposal for a regulation
Article 73 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. *Before adopting a delegated act, the Commission shall consult with the relevant institutions and stakeholders in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.*

Or. en

Amendment 908
Karen Melchior, Yana Toom

Proposal for a regulation
Article 73 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	5. Any delegated act adopted pursuant to Article 4*, Article 5a(1)*, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Or. en

Justification

This amendment gives the Commission the possibility to amend by way of delegated act the annex listing additional banned practices. This future-proofs the legislation.

Amendment 909
Emmanuel Maurel

Proposal for a regulation
Article 83 – paragraph 1

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.	*deleted*
The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.	

Or. fr

Amendment 910
Ibán García Del Blanco, Tiemo Wölken, René Repasi

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	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.

significant change in the design or purpose of the AI system or AI systems concerned.

Or. en

Amendment 911
Sergey Lagodinsky

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 apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX *starting* [12 months after the date of application of this Regulation referred to in Article 85(2)], *or as soon as there is* a significant change in the design or intended purpose of the AI system or AI systems concerned *in which case it shall apply from [the date of application of this Regulation]*.

Or. en

Amendment 912
Sergey Lagodinsky

Proposal for a regulation
Article 83 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The requirements laid down in this Regulation shall be taken into account*, where applicable,* in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.	The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Amendment 913
Sergey Lagodinsky

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 **from**[date of application of this Regulation referred to in Article 85(2)].

Or. en

Amendment 914
Kosma Złotowski

Proposal for a regulation
Article 84 – paragraph 1

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

Or. en

Amendment 915
Emmanuel Maurel

Proposal for a regulation
Article 84 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.	1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation. *These assessments shall be accessible to the public and forwarded to the relevant national authorities. They shall take into account the criteria set out in Article 7(2).*

Or. fr

Amendment 916
Sergey Lagodinsky

Proposal for a regulation
Article 84 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.	1. The Commission shall assess the need for amendment of the list in Annex III *, including the extension of existing area headings or addition of new area headings,* once a year following the entry into force of this Regulation.

Or. en

Amendment 917
Kosma Złotowski

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

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

Or. en

Amendment 918
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
	1b. The Commission shall assess the need for amendment of the list in Annex III every 24 months following the entry into force of this Regulation and until the end of the period of the delegation of power. The findings of that assessment shall be presented to the European Parliament and the Council.

Or. en

Amendment 919
Kosma Złotowski

Proposal for a regulation
Article 84 – paragraph 2

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

Or. en

Amendment 920
Sergey Lagodinsky

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

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

Or. en

Amendment 921
Sergey Lagodinsky

Proposal for a regulation
Article 84 – paragraph 6

Text proposed by the Commission	*Amendment*
6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.	6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources*, including from academia and civil society*.

Or. en

Amendment 922
Sergey Lagodinsky

Proposal for a regulation
Article 84 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Commission shall, if	7. The Commission shall, if

necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology and in the light of the state of progress in the information society.

necessary, submit appropriate proposals to amend this Regulation, in particular taking into account *the effect of AI systems on fundamental rights, equality, and accessibility for persons with disabilities,* developments in technology and in the light of the state of progress in the information society.

Or. en

Amendment 923
Kosma Złotowski

Proposal for a regulation
Annex I – point c

Text proposed by the Commission

(c) Statistical approaches, Bayesian estimation, search and optimization methods.

Amendment

(c) Statistical approaches, Bayesian estimation, *forecasting,* search and optimization methods.

Or. en

Amendment 924
Sergey Lagodinsky

Proposal for a regulation
Annex II – Part A – point 12 a (new)

Text proposed by the Commission

Amendment

12a. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L96/357, 29.3.2014).

Or. en

EN

Amendment 925
Sergey Lagodinsky

Proposal for a regulation
Annex II – Part B – point 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products.

Or. en

Amendment 926
Sergey Lagodinsky

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

Text proposed by the Commission	*Amendment*
1. Biometric identification and categorisation of natural persons:	1. Biometric identification, *biometrics-based data* and categorisation of natural persons:

Or. en

Amendment 927
Kosma Złotowski

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

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

Or. en

Amendment 928
Sergey Lagodinsky

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 929
Emmanuel Maurel

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

Text proposed by the Commission	*Amendment*
	(aa) AI systems that use physical, physiological or behavioural data and biometric data including, but not limited to, biometric identification, categorisation, detection and verification.

Or. fr

Amendment 930
Kosma Złotowski

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

Text proposed by the Commission	*Amendment*
(a) AI systems intended to be used as	(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.

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

Or. en

Amendment 931
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 3 – point a

Text proposed by the Commission	*Amendment*
(a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;	*deleted*

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 932
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 3 – point b

Text proposed by the Commission	*Amendment*
(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions.	*deleted*

Or. en

Amendment 933
Karen Melchior, Yana Toom

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

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

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 934
Karen Melchior, Yana Toom

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

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

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

EN

Amendment 935
Emmanuel Maurel

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 behaviour of persons in such relationships*.	(b) AI intended to be used for *task allocation in* work-related contractual relationships.

Or. fr

Amendment 936
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission	*Amendment*
(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;	*deleted*

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 937
Emmanuel Maurel

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. fr

Amendment 938
Karen Melchior, Yana Toom

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

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 939
Kosma Złotowski

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	(b) AI systems intended to be used to evaluate the creditworthiness of natural persons*,* establish their credit score *or assessment of insurance risk*, with the exception of AI systems put into service by

own use;   small scale providers for their own use;

Or. en

Amendment 940
Emmanuel Maurel

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) AI systems intended to be used to assess insurance premiums and claims;

Or. fr

Amendment 941
Sergey Lagodinsky

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 942
Emmanuel Maurel

Proposal for a regulation
Annex III – paragraph 1 – point 5 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) AI systems intended to be used to

assess medical treatment.

Or. fr

Amendment 943
Sergey Lagodinsky

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 944
Sergey Lagodinsky

Proposal for a regulation
Annex III – paragraph 1 – point 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Use by vulnerable groups or in situations that imply vulnerability
	(a) AI systems intended to be used by children in a way that may seriously affect a child's personal development, such as by educating the child in a broad range of areas not limited to areas which parents or guardians can reasonably foresee at the time of the purchase;
	(b) AI systems, such as virtual assistants, intended to be used by natural persons for taking decisions with regard to their private lives that have legal effects or similarly significantly affect the natural persons;(c) AI systems intended to be used for personalised pricing within the meaning of Article 6 (1) (ea) of Directive 2011/83/EU,[A1]

Amendment 945
Emmanuel Maurel

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 offending or reoffending or the risk for potential victims of criminal offences;	*deleted*

Or. fr

Amendment 946
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point a

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

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 947
Emmanuel Maurel

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. fr

Amendment 948
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 6 – point b

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

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 949
Emmanuel Maurel

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)	*deleted*

EN

*2016/680 or assessing personality traits
and characteristics or past criminal
behaviour of natural persons or groups;*

Or. fr

**Amendment 950
Karen Melchior, Yana Toom**

**Proposal for a regulation
Annex III – paragraph 1 – point 6 – point e**

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

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

**Amendment 951
Karen Melchior, Yana Toom**

**Proposal for a regulation
Annex III – paragraph 1 – point 6 – point f**

Text proposed by the Commission	*Amendment*
(f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;	*deleted*

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 952
Emmanuel Maurel

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. fr

Amendment 953
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 7 – point a

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

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 954
Emmanuel Maurel

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission	*Amendment*
(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;	*deleted*

Or. fr

Amendment 955
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission	*Amendment*
(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;	*deleted*

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 956
Emmanuel Maurel

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	*deleted*

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. fr

Amendment 957
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission	*Amendment*
(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.	*deleted*

Or. en

Justification

Moved to banned practices, explanation provided in amendments there.

Amendment 958
Emmanuel Maurel

Proposal for a regulation
Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. AI systems used to filter the content generated by users on social media and social networks;

Or. fr

Amendment 959

EN

Emmanuel Maurel

Proposal for a regulation
Annex III – paragraph 1 – point 8 b (new)

Text proposed by the Commission	*Amendment*
	8b. AI systems developed or used exclusively for military purposes.

Or. fr

Amendment 960
Karen Melchior, Yana Toom

Proposal for a regulation
Annex III a (new)

Text proposed by the Commission	*Amendment*
	ANNEX IIIa ADDITIONAL PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES REFFERED TO IN ARTICLE 5(1)
	1. Additional Prohibited Artificial Intelligence Practices pursuant to Article 5(1)da are:
	(a) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions.

Or. en

Justification

No AI is currently capable of assessing complex tests. Simple tests can be assessed by simple programmatic logic (Multiple Choice questions, etc...). Developing technology to assess students automatically may result in discrimination based on students' writing style or other factors. Furthermore, only teachers can factor in and evaluate individual students' issues, which is a vital part of education.

Amendment 961

EN

Kosma Złotowski

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

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

Or. en

Amendment 962
Kosma Złotowski

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

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

Or. en

EN

Amendment 963
Emmanuel Maurel

Proposal for a regulation
Annex VI

Text proposed by the Commission	*Amendment*
CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL	*deleted*
1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.	
2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.	
3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.	
4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation.	

Or. fr

Amendment 964
Emmanuel Maurel

Proposal for a regulation
Annex VIII – point 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. If it is used by a public authority or on its behalf, the AI system used, the dates of its use and its purpose;

Amendment 965
Emmanuel Maurel

Proposal for a regulation
Annex VIII – point 11

Text proposed by the Commission	*Amendment*
11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.	*deleted*

Or. fr

EN