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AMENDMENTS
68 - 268

Draft opinion
Susana Solís Pérez
(PE699.056v01-00)

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

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

AM_Com_LegOpinion

Amendment 68
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 for the ***design,*** development, marketing and use of artificial intelligence ***and of sustainable and green artificial intelligence*** in conformity with Union values ***while minimising any risk of adverse and discriminatory impacts on people and adverse impacts on the environment***. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety***,*** and fundamental rights, ***and the protection of environment*** and it ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the ***design,*** development, marketing and use of AI systems, unless explicitly authorised by this Regulation.

Or. en

Amendment 69
Margrete Auken
on behalf of the Greens/EFA Group

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

Or. en

Amendment 70
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1 a) This Regulation should foster a supportive environment for healthier lifestyles in a sustainable and climate neutral way and in particular, facilitate the achievement of the UN Sustainable Development Goals, the Paris Agreement and net-zero transition by 2050 across different sectors. Member States can establish additional requirements other than those established under this Regulation provided they are justified for reasons of public interest, the protection of legal rights, the protection of climate, environment and biodiversity.

Or. en

Amendment 71
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 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.	(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***, end users and end recipients*** throughout the internal market based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for 'real-time' remote biometric identification in publicly accessible spaces for the purpose of law enforcement, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

Or. en

Amendment 72
Margrete Auken

on behalf of the Greens/EFA Group

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. 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 ***food safety, by reducing the use of pesticides, the conservation and restoration of biodiversity and ecosystems, access to and provision of medicines and*** healthcare, ***carbon*** 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 73
Michal Wiezik

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	(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.	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, ***environmental monitoring, nature protection and restoration,*** infrastructure management***, management of natural disasters***, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation.

Or. en

Amendment 74
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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***,*** ***environmental*** and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming ***and food safety***, 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 75
Marie Toussaint, David Cormand

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3 a) In order to ensure the dual ecological and digital transition, secure the technological resilience of the Union and achieve the objectives of the new European Green Deal, sustainability should be at the core at the European AI framework and guarantee that the development of AI is compatible with sustainable environmental resources for current and future generations, at all stages of the lifecycle of AI products; sustainability of AI should encompass sustainable data sources, power supplies and infrastructures;"

Or. en

Amendment 76
Sirpa Pietikäinen, Deirdre Clune, Joanna Kopcińska

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3 a) AI can serve in climate change mitigation for example through the European Union's Earth observation programme Copernicus that has the potential to be the programme needed to acquire accurate scientific information that secures science-based decision-making and implementation of the Union's climate, biodiversity and other environmental policies.

Or. en

Amendment 77
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3 a) Advanced AI solutions for medicines and healthcare should support the fight against disinformation to secure a trustworthy environment for users by providing an effective analysis and tracing of content, correlation and comparison of various sources of information as well as the exploitation or manipulation of contextual information.

Or. en

Justification

Disinformation around vaccines in particular is just one example of cyber-disinformation undermining public trust and public health outcomes.

Amendment 78
Marie Toussaint, David Cormand

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3 b) Studies have shown that the training and use of AI has significant environmental impacts which, if they are left out of the equation, could threaten the EU's objectives under the Green Deal. The environmental impact of AI encompasses both the critical raw material needed to design infrastructures and microprocessors, as well as the energy required by the development, training and use of an AI system. In particular, tuning, meaning the action of re-purposing or refining and AI model,

was found to be even more environmentally costly than training a model in the first place. Best practices in AI sustainability should include a reasonable allocation of resources, consider potential shortages in key critical raw material and limit unnecessary data acquisition and processing.

Or. en

Amendment 79
Sirpa Pietikäinen, Joanna Kopcińska, Deirdre Clune

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3 b) The United Kingdom's withdrawal from the European Union has caused a significant funding gap to the aforementioned Copernicus programme, which endangers the whole future of Copernicus and which needs to be acutely solved by guaranteeing sufficient funds as well as data processing support so that advanced and automatized technology and AI based monitoring and analysing of all central environmental indicators will be guaranteed in the future.

Or. en

Justification

With the UK being unable to participate to the funding of the Copernicus programme at the moment, funding for the programme needs to be found elsewhere and the importance of AI in climate change mitigation acknowledged in the legislation in question to ensure the continuation of this crucial programme. The lack of funding is putting the whole programme at severe risk.

Amendment 80
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3 b) AI applications for medicines and healthcare should support the interoperability of health data and epidemiological information to better provide doctors with the necessary support to diagnose and treat patients more effectively to improve patient outcomes.

Or. en

Amendment 81
Marie Toussaint, David Cormand

Proposal for a regulation
Recital 3 c (new)

Text proposed by the Commission	*Amendment*
	(3 c) To ensure sustainable AI, developers should report key environmental parameters such as training time and resource use, expected energy and data processing required by the use of the AI during its lifetime, and provide carbon emission reports to regulatory authorities in order to enable transparency and comparison between models. Tools for calculating emissions, like the Machine Learning Emission calculator, are already available on the market and should be built upon and systematically used as a matter of transparency requirement and reporting obligations.

Or. en

Amendment 82
Marie Toussaint, David Cormand

Proposal for a regulation

Recital 3 d (new)

Text proposed by the Commission	*Amendment*
	(3 d) Sustainable AI taskforces should be incorporated in national surveillance authorities and in Member State government and relevant national and European agencies, in order to maintain the sustainable development and use of AI.

Or. en

Amendment 83
Marie Toussaint, David Cormand

Proposal for a regulation
Recital 3 e (new)

Text proposed by the Commission	*Amendment*
	(3 e) In order to ensure the compatibility of AI development and sustainability goals, a "proportionality framework" should assess whether the training or the tuning of an AI model for a particular task is proportional to the carbon footprint and environmental impact it would have. Such a scheme should enable certain model training and development to be stopped in case the predicted environmental cost is deemed to exceed the social, environmental and economical benefit or if another non-AI solution with an equivalent level of success is available.

Or. en

Amendment 84
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 ***including climate and the environment***. Such harm might be material or immaterial.

Or. en

Amendment 85
Margrete Auken
on behalf of the Greens/EFA Group

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 ***citizens'*** rights that are protected by Union law. Such harm might be material or immaterial***, direct or indirect***.

Or. en

Amendment 86
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) In terms of environment, artificial intelligence has a strong potential to solve environmental issues such as reducing resource consumption, promoting decarbonisation, boosting the circular

economy, balancing supply and demand in electricity grids or optimising logistic routes. The analysis of large volumes of data can lead to a better understanding of environmental challenges and a better monitoring of trends and impacts. The intelligent management of large volumes of information related to the environment also provides solutions for better environmental planning, decision-making and monitoring of environmental threats and can inform and encourage environmentally sustainable business, providing better information to reorient sustainable decision-making in different business models, and thereby improving the efficiency of resource, energy and material use through smart-Industry initiatives and M2M and IoT technologies.

Or. en

Amendment 87
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) In order to ensure the dual climate and digital transition and secure the technological resilience of the EU and achieve the objectives of the new European Green Deal, sustainability should be at the core at the European AI framework to guarantee that the development of AI is compatible with sustainable development of environmental resources for current and future generations, at all stages of the lifecycle of AI products; sustainability of AI should encompass sustainable data centres, resource use, power supplies and infrastructures.

Or. en

Amendment 88
Deirdre Clune

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) In its communication on "The European Green Deal", the Commission outlined the role of digital technologies such as artificial intelligence, 5G, data, internet of things and cloud and edge computing in achieving a sustainable future.

Or. en

Amendment 89
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4 b) The predictive analytics capabilities provided by artificial intelligence based models can support a better maintenance of energy systems and infrastructure, as well as anticipate the patterns of society's interaction with natural resources, thus facilitating better resource management. Artificial intelligence also has the potential to contribute to strengthening environmental administration and governance by facilitating administrative decisions related to environmental heritage management, monitoring violations and environmental fraud, and encouraging citizen participation in biodiversity conservation initiatives.

Or. en

Amendment 90
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4 b) To ensure sustainable AI, developers should report key environmental parameters such as training time and resource use, the expected costs energy and processing required by the use of the AI during its lifetime, and provide carbon emission reports to regulatory authorities in order to ensure transparency and comparability between models. Tools for calculating emission generated are already available and should be built upon and used within monitoring and reporting obligations.

Or. en

Amendment 91
Deirdre Clune

Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4 b) The Commission in its White Paper on "Artificial Intelligence - A European approach to excellence and trust", states that artificial intelligence can aid in tackling the most pressing concerns, such as climate change and environmental degradation.

Or. en

Amendment 92
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 4 c (new)

Text proposed by the Commission	*Amendment*
	(4 c) However, despite the high potential solutions to the environmental and climate crisis offered by artificial intelligence, the design, training and execution of algorithms imply a high energy consumption and consequently high levels of carbon emissions. These environmental and carbon footprints are expected to increase overtime as the volume of data transferred and stored and the increasing development of AI applications will continue to grow exponentially in the years to come. In order to favour the ecological transition and the reduction of the carbon footprint of artificial intelligence this regulation contributes to the promotion of a green and sustainable artificial intelligence and to the consideration of the environmental impact of AI systems throughout their lifecycle.

Or. en

Amendment 93
Deirdre Clune

Proposal for a regulation
Recital 4 c (new)

Text proposed by the Commission	*Amendment*
	(4 c) Artificial intelligence use can be of significant environmental and economic value in contributing to the fight against climate change possessing the potential to reduce global greenhouse gases by 1.5 - 4.0% by 2030. While AI systems themselves need to be designed sustainably, it has also been estimated

that ICT technologies are capable of reducing ten times more greenhouse gas emissions than their own footprint[1a].

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1a

https://www.europarl.europa.eu/cmsdata/231979/Working%20Paper%20-%20AIDA%20Hearing%20on%20AI%20and%20Green%20Deal.pdf

Or. en

Amendment 94
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 4 d (new)

Text proposed by the Commission	*Amendment*
	(4 d) In terms of health and patients' rights, AI systems can play a major role in improving the health of individual patients and the performance of public health systems. However, when AI is deployed in the context of health, patients may be exposed to potential specific risks that could lead to physical or psychological harm, for example, when different biases related to age, ethnicity, sex or disabilities in algorithms leads to incorrect diagnoses. The lack of transparency around the functioning of algorithms also makes it difficult to provide patients with the relevant information they need to exercise their rights, such as informed consent. In addition, AI's reliance on large amounts of data, many of them being personal data, may affect the protection of medical data, due to patients' limited control over the use of their personal data and the cybersecurity vulnerabilities of AI systems. All of this means that special caution must to be taken when AI is applied in clinical or healthcare settings.

Amendment 95
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems 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] .	(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the ***design,*** development, use and uptake of ***sustainable and green*** artificial intelligence in the internal market ***aligned with the European Green Deal provisions,*** that at the same time meets a high level of protection of public interests, such as health and safety***, environment and climate change, food security*** and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, 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).

Or. en

Amendment 96
Stelios Kympouropoulos

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems 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] .	(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market and putting into service of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. By laying down those rules, this Regulation supports the objective of the Union of being a global leader in the development of secure, ***non-biased*** trustworthy and ethical artificial intelligence, as stated by the European Council[33], and it ensures the protection of ethical principles, as specifically requested by the European Parliament[34] .
[33] European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.	[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	[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).

aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

Or. en

Amendment 97
Stelios Kympouropoulos

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.	(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments***, such as neurotechnology, which may put mental privacy at risk and require legislative proposals to protect neurodata and other sensitive health data***. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

Or. en

Amendment 98
Michal Wiezik

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.	(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, ***evaluation of status and quality,*** predictions***, potential risks***, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list.

Or. en

Amendment 99
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with which the system interacts, be it in a physical or digital dimension. AI systems can be designed to operate with varying levels of autonomy and be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serve the functionality of the product without being integrated therein (non-embedded). The definition of AI system should be complemented by a list of specific techniques and approaches used for its development, which should be kept up-to–date in the light of market and technological developments through the ***adoption of delegated acts by the Commission*** to amend that list.	(6) The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments. The definition should be based on the key functional characteristics of the software, in particular the ability, for a given set of 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 ***ordinary legislative procedure*** to amend that list.

Or. en

Justification

The list of techniques and approaches is an essential element of this regulation as it entitles the definition of what an AI system is, determining the scope of the Regulation. Article 290 TFEU establishes that the delegation of powers is for non-legislative acts to supplement or amend certain non-essential elements; and that essential elements shall be reserved for the legislative act and shall not be delegated. It also stipulates that legislative acts implementing delegation of power must include the duration of this delegation. This is not the case for Article 4.

Amendment 100
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 ***or the environment***, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) and should be non-discriminatory and in line with the Union's international trade commitments.

Or. en

Amendment 101
Deirdre Clune

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13 a) Artificial intelligence has the potential to unlock solutions saving millions of lives through early and accurate detection of diseases, tailored treatment and enhanced quality of care to patients. The use of AI in the health sector can reduce the costs of health services and medical care.

Or. en

Amendment 102
Deirdre Clune

Proposal for a regulation
Recital 13 b (new)

Text proposed by the Commission	*Amendment*
	(13 b) In order to improve the health

outcomes of the population in EU Member States, it is essential to have a clear liability framework in place for AI medical applications and medicine development.

Or. en

Amendment 103
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 21

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

Or. en

Amendment 104
Marie Toussaint, David Cormand

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 ***climate priorities, environmental imperatives and*** public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety**,** ***greenhouse gas emissions, crucial environmental parameters like biodiversity or soil pollution*** and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 105
Margrete Auken
on behalf of the Greens/EFA Group

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	(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.	Union ***climate priorities and*** public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety***, greenhouse gas emissions*** and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 106
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 ***or the environment*** in the Union and such limitation minimises any potential restriction to international trade, if any.

Or. en

Amendment 107
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27 a) The environmental sustainability of AI technologies and data centres is essential to mitigate the high carbon footprint though increased computational energy consumption and high energy costs to the volume of data stored, the amount of heat, electric and electronic waste generated, resulting in increased pollution. It is therefore important to minimise the climate and environmental footprint of AI and related technologies.

Or. en

Amendment 108
Joanna Kopcińska

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	(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions

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

should be reliable and accurate***. Digital health should not dehumanise care nor diminish the doctor-patient relationship, but should provide doctors with assistance in diagnosing and/or treating patients more effectively, all the while keeping in mind the necessary human oversight and abiding by relevant data protection rules***. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.

Or. en

Amendment 109
Margrete Auken
on behalf of the Greens/EFA Group

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 Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require	(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require

consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection 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.

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***, the right to a healthy, toxic free environment and the ability to effectively address climate change***.

Or. en

Amendment 110
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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	(28) AI systems could produce adverse outcomes to health and safety of persons ***or to the environment***, in particular when such systems operate as components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. The extent

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

Amendment 111
Stelios Kympouropoulos

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	(28) AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products. Consistently with

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

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

that an AI system can cause, including in relation to the health and safety of persons.

that an AI system can cause, including in relation to the health and safety of persons.

Or. en

Amendment 112
Deirdre Clune

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) The classification of an AI system as high-risk pursuant to this Regulation should not ***necessarily*** mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[47] and Regulation (EU) 2017/746 of the European Parliament and of the Council[48] , where a third-party conformity assessment is provided for medium-risk and high-risk products.	(31) The classification of an AI system as high-risk pursuant to this Regulation should not***, unless duly justified,*** mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[47] and Regulation (EU) 2017/746 of the European Parliament and of the Council[48], where a third-party conformity assessment is provided for medium-risk and high-risk products. ***To ensure consistency and legal clarity, where the provided risk-based system already takes into account potential associated risks, AI components should continue to be assessed as part of the overall device.***
[47] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	[47] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).
[48] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC	[48] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC

and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).	and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Amendment 113
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Or. en

Amendment 114
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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	(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.	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 ***or the environment*** at large scale and lead to appreciable disruptions in the ordinary conduct of social and economic activities.

Or. en

Amendment 115
Joanna Kopcińska

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination.	(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. ***It requires appropriate training and preparation for health and administrative personnel to prevent a digital divide, specifically bearing in mind our ageing societies and potential challenges to healthcare systems in the post-pandemic world.*** 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.

Or. en

Amendment 116
Stelios Kympouropoulos

Proposal for a regulation
Recital 37

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

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

Or. en

Amendment 117
Stelios Kympouropoulos

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

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.

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.

Or. en

Amendment 118
Deirdre Clune

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI	(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

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 ***healthcare,*** 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***, health*** 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.

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 119
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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	(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.	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 ***or the environment***.

Or. en

Amendment 120
Joanna Kopcińska

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity***, as well as related serious ethical concerns regarding***

to assist judicial authorities in researching and interpreting facts and the law and in applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

machine autonomy and decision-making, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Or. en

Amendment 121
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40 a) AI systems not covered by Regulation (EU) 2017/745 with an impact on health or healthcare should be classified as high-risk and be covered by this Regulation. Healthcare is one of the sectors where many AI applications are being deployed in the Union and is a market posing potential high risk to human health. Regulation (EU) 2017/745 only covers medical devices and software with an intended medical purpose, but excludes many AI applications used in health, like AI administrative and management systems used by healthcare professionals in hospitals or other healthcare setting and by health insurance companies and many fitness and health apps which provides AI powered recommendations. These applications may present new challenges and risks to people, because of their health effects or the processing of

sensitive health data. In order to control this potential specific risks that could lead to any physical or psychological harm or the misuse of sensitive health data, these AI systems should be classified as high-risk.

Or. en

Amendment 122
Joanna Kopcińska

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.	(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider ***and the digital services should not dehumanise care nor diminish any human relationship, but should provide assistance in a more effective way***.

Or. en

Amendment 123
Deirdre Clune

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and	(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human 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.	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. ***To avoid any potential misalignment or duplication, the Commission should clearly determine where any relevant sectoral legislation may take precedence concerning data governance and any associated management practices or quality criteria.***

Or. en

Amendment 124
Joanna Kopcińska

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 ***(threatening patient preference, and privacy)***, 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. en

Amendment 125
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 43

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

Or. en

Amendment 126
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

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

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

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

Or. en

Amendment 127
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44 a) These requirements should also take into account the international environmental and human rights principles and instruments including the UNECE convention on access to information, public participation on decision making and access to justice in environmental matters (Aarhus Convention), Resolution 48/13 adopted by the Human Rights Council on 8 October 2021 on the human right to a clean, healthy and sustainable environment, as well as international climate commitments outlined in the 2018 IPCC Special Report to limit global average temperatures to 1.5

degrees.

Or. en

Amendment 128
Deirdre Clune

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.	(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to ***have increased*** access and use ***of*** high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems.

Or. en

Amendment 129
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 45 a (new)

Text proposed by the Commission	*Amendment*
	(45 a) To promote the sustainable development of AI systems and in particular to prioritise the need for sustainable, energy efficient data centres, requirements for efficient heating and cooling of data centres should be consistent with the long-term climate and environmental priorities of the Union and comply with the principle of 'do no significant harm' within the meaning of Regulation (EU) 2020/852 and should be fully decarbonised by January 2050. In this regard, Member States and telecommunications providers should collect and publish information relating to the energy performance and environmental footprint for AI technologies and date centres including information on the energy efficiency of algorithms to establish a sustainability indicator for AI technologies.

Or. en

Justification

JRC publication on a European Code of Conduct for Data Centre Energy Efficiency
https://publications.jrc.ec.europa.eu/repository/handle/JRC106379

Amendment 130
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 45 b (new)

Text proposed by the Commission	*Amendment*
	(45 b) A European Code of Conduct for

data centre energy efficiency can establish key sustainability indicators to measure four basic dimensions of a sustainable data centre, namely, how efficiently it uses energy, the proportion of energy generated from renewable energy sources, the reuse of any waste and heat and the usage of freshwater.

Or. en

Amendment 131
Margrete Auken
on behalf of the Greens/EFA Group

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 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 ***that should include a multicriteria environmental lifecycle assessment*** 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.

Or. en

Amendment 132
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 information on how high-risk AI systems have been ***designed and*** developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Or. en

Amendment 133
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46 a) Artificial intelligence should contribute to the European Green Deal and the green transition and be used by governments and businesses to benefit people and the planet, and contribute to the achievement of sustainable development, the preservation of the environment, climate neutrality and circular economy goals. The design, development, deployment and use of AI systems should also minimise and remedy any harm caused to the environment during their lifecycle and across their entire supply chain in line with Union law. In this regard, in order to enhance

sustainability and ecological responsibility, and to design, develop, deploy and use ever greener and more sustainable AI systems, green AI should be encouraged. Green AI proposes to reduce energy consumption by balancing the volume of data needed to train a model, the amount of time to train it and the number of iterations to optimise its parameters, being more efficient and less carbon intensive, and by promoting the use of renewable energy sources in the creation and application of these models.

Or. en

Amendment 134
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46 a) The multicriteria lifecycle assessment should contain specific information on the computational resources used for system development including performance, frequency and energy usage for algorithmic training, re-training and fine tuning and a quantitative assessment of how the system affects climate change mitigation and adaption, including greenhouse gas emissions that result from the AI system.

Or. en

Amendment 135
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 46 b (new)

Text proposed by the Commission	*Amendment*
	(46 b) In order to promote the development of a green and sustainable artificial intelligence, as well as to address needs of the providers and product manufacturers to carry out the ecological transition and green transformation, the technical documentation of high-risk AI systems should also include an "energy efficiency and carbon intensity marking", indicating the energy used in the training and execution of algorithms and the carbon intensity. This will stimulate research into new modelling and running strategies and algorithms that lower the energy use and the carbon intensity. In this regard, high-risk AI systems that boost the energy efficiency of data storage and computing systems, and minimise its own carbon footprint will obtain a "green AI label". Likewise, non high-risk AI systems which address global challenges related to climate and environment and support the implementation of pertinent initiatives and actions such as the Paris Agreement, the UN Sustainable Development Goals and the European Green Deal, may also receive the green AI label.

Or. en

Amendment 136
Deirdre Clune

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	(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.

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. ***Appropriate human oversight and any subsequent intervention should not result in the intended function of the AI system being affected in a way that risks health, safety or fundamental rights, as applicable in the light of the intended purpose of the system.***

Or. en

Amendment 137
Joanna Kopcińska

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48 a) The recommendations regarding human oversight from the Opinion of the Committee on the Environment, Public Health and Food Safety for the Committee on Legal Affairs with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL)) are to complement this Regulation.

Or. en

Amendment 138
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation

Recital 49

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

Or. en

Amendment 139
Deirdre Clune

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 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. ***Where this overlaps with any relevant and applicable sectoral legislation, the relevant terminology should be appropriately harmonised to avoid any unnecessary fragmentation.***

Or. en

Amendment 140
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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***, including the energy consumption and carbon intensity of the system*** 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.

Or. en

Amendment 141
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 55

Text proposed by the Commission	*Amendment*
(55) Where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial legislation is not placed on the market or put into service independently from the product, the manufacturer of the final product as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established	(55) Where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial legislation is not placed on the market or put into service independently from the product, the manufacturer of the final product as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established

in this Regulation and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.	in this Regulation***, including the information about the energy consumption and carbon intensity of the component,*** and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.

Or. en

Amendment 142
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) Insofar the Union lacks a charter of digital rights that would provide a reference framework for guaranteeing citizens' rights in the new digital reality and that would safeguard fundamental rights in the digital landscape. A number of AI-related data-protection issues may lead to uncertainties and costs, and may hamper the development of AI applications. In this regard, some provisions are included in the text to ensure the explanation, acceptability, surveillance, fairness and transparency of the AI systems.

Or. en

Amendment 143
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) In order to ensure a high level of trustworthiness of high-risk AI systems,	(62) In order to ensure a high level of trustworthiness of high-risk AI systems,

those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.	those systems should be subject to a conformity assessment prior to their placing on the market or putting into service. ***The assessment should comprise an obligatory multicriteria, environmental life cycle assessment based on the four life-cycle phases, manufacturing, distribution, use phase and end of life phase.***

Or. en

Amendment 144
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 ***as well as the energy efficiency and carbon intensity marking***. 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 ***and the energy efficiency and carbon intensity marking***.

Or. en

Amendment 145
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 68

Text proposed by the Commission	*Amendment*
(68) Under certain conditions, rapid availability of innovative technologies may	(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.

be crucial for health and safety of persons***, the environment and climate change*** and for society as a whole. It is thus appropriate that under exceptional reasons of public security or protection of life and health of natural persons***, the protection of the environment*** and the protection of industrial and commercial property, Member States could authorise the placing on the market or putting into service of AI systems which have not undergone a conformity assessment.

Or. en

Amendment 146
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 147
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 71

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

Or. en

Amendment 148
Margrete Auken
on behalf of the Greens/EFA Group

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 ***and effective*** forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof 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 149
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Recital 73 a (new)

Text proposed by the Commission	*Amendment*
	(73 a) In order to promote a more sustainable and greener innovation, the Commission and Member States should publish guidelines and methodologies for efficient algorithms that provide data and pre-trained models in view of a rationalisation of training activity. The development of best practice procedures would also support the identification and subsequent development of solutions to the most pressing environmental challenges of AI systems, including on the development of the previously mentioned green AI label.

Or. en

Amendment 150
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, ***including on*** technical specifications ***or*** existing standards regarding the requirements established in this Regulation and ***providing*** advice to and assisting the Commission on specific questions related to artificial intelligence.	(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, ***the establishment of an AI sustainability taskforce for the sustainable development of AI and the development towards a harmonised criteria for sustainable*** technical specifications***,*** existing standards ***and best practice*** regarding the requirements established in this Regulation and ***to provide expert*** advice to and assisting the Commission on specific questions related to artificial intelligence ***to better address emerging cross-border challenges arising from rapid technological development***.

Or. en

Amendment 151
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission	*Amendment*
	(77 a) In order to ensure the

compatibility of AI development, climate and sustainability goals are met, a "proportionality framework" should assess whether the training or the fine-tuning of an AI model for a particular task is proportionate to the carbon footprint and environmental impact it represents. Such a scheme should enable certain model training, fine-tuning and development to be stopped in event that the predicted environmental cost is deemed to exceed the social, environmental and/or economic benefit and where alternative digital solutions with an equivalent level of success are available.

Or. en

Amendment 152
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 resulting from the use of their AI systems. ***Likewise, civil society organisations and other stakeholders***

should be enabled to provide input and lodge complaints if the protection of fundamental rights or public interest is at risk.

Or. en

Amendment 153
Margrete Auken
on behalf of the Greens/EFA Group

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

Or. en

Amendment 154
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Or. en

Amendment 155
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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	(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.

accordance with Article 290 TFEU should be delegated to the Commission to amend the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII**,**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 ***and the provisions setting the content and presentation of the information, the methodology procedures, the minimum standards and the efficiency scale for the energy efficiency and carbon intensity marking and the green AI label of article 49a***. 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.

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58 OJ L 123, 12.5.2016, p. 1.

Or. en

Justification

The list of techniques and approaches is an essential element of this regulation as it entitles the definition of what an AI system is, determining the scope of the Regulation. Article 290 TFEU establishes that the delegation of powers is for non-legislative acts to supplement or amend certain non-essential elements; and that essential elements shall be reserved for the legislative act and shall not be delegated. It also stipulates that legislative acts implementing

delegation of power must include the duration of this delegation. This is not the case for Article 4.

Amendment 156
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 85 a (new)

Text proposed by the Commission	*Amendment*
	(85 a) The list of high-risk AI systems included in Annex III should build on four types of sources and evidence, namely: i) existing EU legislation, ii) scientific evidence and data concerning particularly high levels of human, climate and environmental risk, iii) sectors that are already considered "high-risk" under international standards, and iv) sectors that are already considered "high-risk" under emerging markets or business initiatives.

Or. en

Amendment 157
Margrete Auken
on behalf of the Greens/EFA Group

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 ***to ensure the protection for the public interest, the health and safety of consumers and the protection of the environment*** for the placing on the market, the putting into service and the use of artificial intelligence systems (‘AI systems’) in the Union;

Or. en

Amendment 158
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
	(a a) harmonised rules and procedures to establish an energy efficiency and carbon intensity marking and green labelling to mitigate the environmental impact of AI systems enabling further sustainability;

Or. en

Amendment 159
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
	(1 a) "sustainable and green artificial intelligence" means an artificial intelligence system that reduces energy consumption by balancing the volume of data needed to train a model, the amount of time to train it and the number of iterations to optimise its parameters, thus reducing its carbon intensity;

Or. en

Amendment 160
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

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

Or. en

Amendment 161
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 162
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	(14 a) 'AI sustainability' means an assessment of how an AI system broadly affects or may affect climate change mitigation and adaption, including greenhouse gas emissions that result from the applications of the AI system. The assessment should be quantitative and describe the methodology and

assumptions used including, specific information on computing power required for system development, patterns of usage, frequency of training and fine-tuning, as well as information relating the model architecture and to the type and location of computing infrastructure used;

Or. en

Amendment 163
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 3 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24 a) "energy efficiency and carbon intensity marking" means a marking by which a provider indicates the carbon footprint of an AI system calculated by estimating the power consumption of the algorithms training and execution and the carbon intensity of producing this energy;

Or. en

Amendment 164
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 3 – paragraph 1 – point 24 b (new)

Text proposed by the Commission	*Amendment*
	(24 b) "green AI label" means a label by which the less carbon intensive and most energy efficient AI systems are recognised and that promotes the techniques and procedures used for a better efficiency;

Or. en

Amendment 165
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 3 – paragraph 1 – point 28

Text proposed by the Commission	*Amendment*
(28) 'common specifications' means a document, other than a standard, containing technical solutions providing a means to, comply with certain requirements and obligations established under this Regulation;	(28) 'common specifications' means a document, other than a standard, containing technical solutions providing a means to, comply with certain requirements and obligations established under this Regulation ***and horizontal Union legislation***;

Or. en

Amendment 166
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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.	***For the amendment of*** 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 ordinary legislative procedure should be followed***.

Or. en

Justification

The list of techniques and approaches is an essential element of this regulation as it entitles the definition of what an AI system is, determining the scope of the Regulation. Article 290 TFEU establishes that the delegation of powers is for non-legislative acts to supplement or amend certain non-essential elements; and that essential elements shall be reserved for the legislative act and shall not be delegated. It also stipulates that legislative acts implementing delegation of power must include the duration of this delegation. This is not the case for Article 4.

Amendment 167
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Justification

Discriminatory AI driven price optimisation strategies should not be permitted. For example: insurance firms targeting price increases at consumers who are perceived by AI systems as less likely to switch providers

Amendment 168
Margrete Auken
on behalf of the Greens/EFA Group

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

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

physical or psychological harm;

Or. en

Justification

The protection of vulnerable citizens should include those suffering from temporary vulnerabilities including addiction or bereavement to ensure protection from the use of AI driven persuasion profiling used in dating and gambling websites for example.

Amendment 169
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 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.

Or. en

Amendment 170
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 171
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	(b a) An AI system that has a significantly high impact on the environment, broadly affecting climate change mitigation and adaption, including greenhouse gas emissions that result from the applications of the AI system.

Or. en

Amendment 172
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 intended to be used in any of the areas listed in points 1 to ***9*** of Annex III;

Or. en

Amendment 173
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 174
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Or. en

Amendment 175
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 176
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Or. en

Amendment 177
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 178
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

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

Or. en

Amendment 179
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 180
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 181
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

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

shall not be considered as easily reversible;

Or. en

Amendment 182
Margrete Auken
on behalf of the Greens/EFA Group

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

Or. en

Amendment 183
Margrete Auken
on behalf of the Greens/EFA Group

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) have a significantly high impact on the environment through, inter alia, its computer-related energy consumption, efficiency in data use, when compared with other, state-of-the-art AI systems; or may result in significant environmental impacts or greenhouse gas emissions

through the way it is applied.

b) be accessed by or have an impact on children.

Or. en

Amendment 184
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	(g a) (h) key environmental indicators, carbon reporting, greenhouse gas emissions, optimisation of data storage and energy consumption and best practices in terms of resource use;

Or. en

Amendment 185
Deirdre Clune

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Training, validation and testing data sets ***shall*** be relevant, representative, free of errors ***and*** complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.	3. Training, validation and testing data sets ***should*** be relevant, representative, free of errors***,*** complete ***and consistent with the generally acknowledged state of the art***. 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 186
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 10 – paragraph 5

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

Or. en

Amendment 187
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10 a
	Environmental Impact
	1. High-risk systems shall be designed and developed to make use of state-of-the-art methods and best practices to reduce greenhouse gas emissions, computational complexities, increase energy efficiency and the efficiency of data of the system in

productive use. This includes techniques involving the training and re-training or models.

They shall be developed and established with capabilities that enable the measurement of the energy consumed and/or other environmental impact that the productive use of the systems may have.

2. Providers of high-risk AI systems shall perform an environmental sustainability assessment over its entire lifecycle. The Commission shall adopt delegated acts in accordance with Article 73 of this Regulation to provide reliable, accurate and reproducible standards and methods for the environmental sustainability assessment to take into account recognised state-of-the-art measurement methods, or new methods that enable the comparison of the environmental impact of AI systems.

The data must be understandable, relevant, representative, verifiable, comparable and represented in a faithful manner.

The assessment shall include information relating to:

(a) energy consumption;

(b) greenhouse gas emissions;

(c) water and marine resources;

(d) resource use, including rare metals, minerals and the circular economy;

(e) pollution;

(f) biodiversity and ecosystems.

3. The assessment shall be structured in a standardised, machine readable and interoperable format that allows for publication and further comparability analysis.

4. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IIIa where necessary to ensure that, in the light of technical

progress, the environmental impact measurement is complete and comparable.

Or. en

Amendment 188
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements ***as well as their energy consumption and carbon intensity information***. It shall contain, at a minimum, the elements set out in Annex IV.

Or. en

Amendment 189
Margrete Auken
on behalf of the Greens/EFA Group

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’) while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications ***especially in relation to energy efficiency, resource use,***

greenhouse gas emissions and the sustainability of data centres.

Or. en

Amendment 190
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

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***, including in relation to possible risks to fundamental rights and discrimination***.

Or. en

Amendment 191
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

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

Or. en

Amendment 192
Margrete Auken

on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	(v a) (vi) Key environmental performance indicators during training and fine-tuning of the AI system during the use phase which should form a multicriteria life-cycle assessment report and consider the material climate and energy impact of the AI system.

Or. en

Amendment 193
Marie Toussaint, David Cormand

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

Text proposed by the Commission	*Amendment*
	(v a) key environmental performances during the training and expected during the using phase in the form of a multicriteria life-cycle assessment report considering the material and energy impact of the AI system.

Or. en

Amendment 194
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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	2. Human oversight shall aim at preventing or minimising the risks to health, safety***,*** fundamental rights ***and the environment*** that may emerge when a

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.

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 195
Margrete Auken
on behalf of the Greens/EFA Group

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

Or. en

Amendment 196
Deirdre Clune

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 ***provided that this does not result in the intended function of the AI system being affected***

in a way that risks health, safety or fundamental rights.

Or. en

Amendment 197
Marie Toussaint, David Cormand

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

Text proposed by the Commission	*Amendment*
	4 a. High-risk AI shall be designed and trained according to sustainability standards with regard to their material and energy resource consumption. The Commission shall develop a "proportionality framework" assessing whether the training or the tuning of an AI model for a particular task is proportional to the carbon footprint and environmental impact it would have. Such a scheme shall enable model training and development to be stopped in case the predicted environmental cost is deemed to exceed the social, environmental and economic demonstrated benefit or if another non-AI solution with an equivalent level of success is available.

Or. en

Amendment 198
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	4 a. High-risk AI shall be designed and trained according to sustainability standards with regard to their material and energy resource consumption. The

Commission shall develop a "proportionality framework" assessing whether the training or the tuning of an AI model for a particular task is proportional to the carbon footprint and the environmental impact. Such a scheme shall enable model training and development to cease in the event that the predicted environmental cost is deemed to exceed the social, environmental and economic benefit or if another non-AI solution with an equivalent level of success is available.

Or. en

Amendment 199
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
(i) to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;	(i) to affix the CE ***marking and the energy efficiency and carbon intensity*** marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49 ***and their energy consumption and carbon intensity in accordance with article 49a, respectively***;

Or. en

Amendment 200
Joanna Kopcińska

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	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.

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. ***The need for a regulatory framework stipulating the ethical principles to be applied to the design, development, implementation and functioning of all this technology - from data access to strict outcome monitoring.***

Or. en

Amendment 201
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 26 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.	(c) the system bears the required conformity marking and is accompanied by the required ***concise and clear*** documentation and instructions of use***, including in relation to possible risks to fundamental rights and discrimination***.

Or. en

Amendment 202
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system	1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system

bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the obligations set out in this Regulation.	bears the required CE conformity marking ***and the energy efficiency and carbon intensity marking***, that it is accompanied by the required ***concise and clear*** documentation and instruction of use***, including in relation to possible risks to fundamental rights and discrimination***, and that the provider and the importer of the system, as applicable, have complied with the obligations set out in this Regulation.

Or. en

Amendment 203
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring.	1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring***, including the energy efficiency and carbon intensity information***.

Or. en

Amendment 204
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	4 a. Notified bodies shall perform the environmental sustainability life-cycle assessment referred to in Article 43.

Or. en

Amendment 205
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	The Commission shall develop harmonised environmental sustainability requirements for AI systems, their development and use after consultation with relevant stakeholders, including businesses, NGOs, experts and academics.

Or. en

Amendment 206
Marie Toussaint, David Cormand

Proposal for a regulation
Article 41 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. The Commission shall develop sustainability standard requirement for AI systems and AI development practices after consultation of relevant stakeholders, including businesses, NGOs, AI and sustainability experts and academics.

Or. en

Amendment 207
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 points 2 to ***9*** of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.

Or. en

Amendment 208
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 43 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.	4. High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user. ***For the purpose of an environmental conformity assessment, the provider shall perform a multicriteria life-cycle assessment reporting considering the material emissions and energy impact of the all life stages of the AI system.***

Or. en

Amendment 209
Marie Toussaint, David Cormand

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

Text proposed by the Commission	*Amendment*
	4 a. For the purpose of environmental conformity assessment, the provider shall perform a multicriteria life-cycle assessment reporting considering the material and energy impact of the all life stages of the AI system.

Or. en

Amendment 210
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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.	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***, to the environment*** and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies.

Or. en

Amendment 211
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation

Article 49 a (new)

Text proposed by the Commission	*Amendment*
	Article 49 a
	Energy efficiency and carbon intensity marking and green AI label
	1. Based on the energy efficiency and carbon intensity information provided following Article 11(1) and Annex IV, high-risk AI systems shall be affixed an energy efficiency and carbon intensity marking which considers the carbon footprint of the system based on its energy consumption and the carbon intensity.
	2. The least carbon intensive and most energy efficient AI systems shall also be affixed a Green AI label. Non high-risk AI systems other than high-risk AI systems aimed at supporting the green transition may also be affixed a Green AI label upon presentation of the energy efficiency and carbon intensity information by the provider.
	3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to supplement paragraphs 1 and 2 of this Article to specify the content and presentation of the information to be disclosed pursuant to those paragraphs, including the methodology to be used in order to comply with them, the procedure, the minimum standards and the efficiency scale, taking into account the obligations and procedures established pursuant to this Regulation, including the structures and the notifying authorities and notified bodies. The Commission shall adopt that delegated act within a year of the entry into force of this Regulation.
	4. The obligation to provide the energy efficiency and carbon intensity information will not become effective until the adoption of this delegated act.

Or. en

Amendment 212
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

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***, especially in the healthcare sector***, unless this is obvious from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.

Or. en

Amendment 213
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
	3 a. Recipients of an AI system in the domain of healthcare shall be informed of their interaction with an AI system.

Or. en

Amendment 214
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
	3 b. Public and administrative authorities which adopt decisions with the assistance of AI systems shall provide a clear and intelligible explanation which shall be accessible for persons with disabilities and other vulnerable groups.

Or. en

Amendment 215
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 53 – paragraph 3

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

Or. en

Amendment 216
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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***	3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety***, to***

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.	fundamental rights ***or to the environment*** identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.

Or. en

Amendment 217
Edina Tóth

Proposal for a regulation
Article 53 – paragraph 4

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

Or. en

Justification

Sandboxes are controlled testing environments that allow developing, testing and re-testing of AI systems. As such, one aim of the sandbox is to identify potential issues and gaps, and as a second step, to solve the issues (be it with training data, coding, or proposed application), and establish the compliant ways of functioning of the AI systems. Developers of AI systems could easily be discouraged from participation knowing that they remain fully liable for an AI system in a test environment.

Amendment 218
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 53 – paragraph 4

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 219
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 53 – paragraph 5

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

Or. en

Amendment 220
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
(ii) public safety and public health, including disease prevention, control and treatment;	(ii) public safety and public health, including disease prevention, control and treatment***, and the health challenges in relation to the inter-linkage between human and animal health, in particular zoonotic diseases***;

Or. en

Amendment 221
Deirdre Clune

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

Text proposed by the Commission	*Amendment*
(ii) public safety and public health, including disease prevention, control and treatment;	(ii) public safety and public health, including disease ***detection, diagnosis,*** prevention, control and treatment;

Or. en

Amendment 222
Margrete Auken
on behalf of the Greens/EFA Group

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

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

Or. en

Amendment 223
Marie Toussaint, David Cormand

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

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

Or. en

Amendment 224
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
(iii) a high level of protection and improvement of the quality of the environment;	(iii) a high level of protection and improvement of the quality of the environment***, with particular emphasis on the three global environmental challenges: climate change, biodiversity loss and pollution***;

Or. en

Amendment 225
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	(iii a) the principle of data minimisation shall be upheld, meaning that the data acquisition and processing shall be kept to

what is strictly necessary for the purpose of the AI application;

Or. en

Amendment 226
Marie Toussaint, David Cormand

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

Text proposed by the Commission	*Amendment*
	(a a) the principle of data minimisation should be upheld, and the data acquisition and processing shall be kept to what is strictly necessary for the purpose of the AI application;

Or. en

Amendment 227
Edina Tóth

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

Text proposed by the Commission	*Amendment*
	(g a) any personal data processed in the context of the sandbox is safeguarded with appropriate technical measures, such as encryption or anonymisation techniques.

Or. en

Justification

Since Article 55 is in itself a broad interpretation of the purpose compatibility as defined in Article 6 (1) b) and (4) in the GDPR, special attention should be taken to the application of technical safeguards for processing the personal data, that should be reiterated in this list. The addition of "anonymisation techniques" is of outmost importance in order to remain technologically neutral, and not to cause confusion with the list of Annex I.

Amendment 228
Edina Tóth

Proposal for a regulation
Article 55 – title

Text proposed by the Commission	*Amendment*
Measures for ***small-scale*** providers and users	Measures for ***SME*** providers and users

Or. en

Amendment 229
Edina Tóth

Proposal for a regulation
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The specific interests and needs of the ***small-scale*** providers shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size and market size.	2. The specific interests and needs of the ***SME*** providers ***in relation to their size, annual turnover or similar indicator*** 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

Justification

To achieve the objective set out in Article 55 (1) a), it is worth considering adding a threshold to Article 55(2) e.g., based on the number of employees or annual turnover, to exempt the smallest companies and entrepreneurs from paying any fees related to the conformity assessment requirements of the Regulation.

Amendment 230
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 56 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*

(c a) assist the Commission in the field of international cooperation in artificial intelligence for matters covered by this Regulation.

Or. en

Amendment 231
Marie Toussaint, David Cormand

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 ***shall*** be invited to the meetings, where the issues discussed are of relevance for them. ***A sustainable AI taskforce comprised of independent digital sustainability experts shall be established within the board to ensure the systemic consideration and inclusion of the EU's environmental imperatives within the regulation of AI.***

Or. en

Amendment 232
Margrete Auken
on behalf of the Greens/EFA Group

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.	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.	Other national authorities ***shall*** be invited to the meetings, where the issues discussed are of relevance for them. ***A sustainable AI taskforce composed of independent digital sustainability experts shall be established within the Board to ensure the due consideration and inclusion of the Union's environmental priorities within the regulatory framework of AI systems.***

Or. en

Amendment 233
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 57 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.	4. The Board may invite external experts***, ethicists, civil society organisations including consumer associations, human rights groups and intergovernmental organisations*** 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.

Or. en

Amendment 234
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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	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.	and may hold exchanges with interested third parties ***of a wide array of organisations*** to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Or. en

Amendment 235
Edina Tóth

Proposal for a regulation
Article 58 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) collect and share expertise and best practices among Member States;	(a) collect and share ***technical and regulatory*** expertise and best practices among Member States;

Or. en

Justification

It should be specified that the technical as well as from the regulatory views are considered.

Amendment 236
Margrete Auken
on behalf of the Greens/EFA Group

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) ***conduct independent expert evaluations,*** issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, in particular

Or. en

Amendment 237
Margrete Auken
on behalf of the Greens/EFA Group

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 ***and horizontal Union legislation***. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their activities and tasks ***to avoid any conflicts of interest***.

Or. en

Amendment 238
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 59 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.	4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, ***environment,*** health and safety risks and knowledge of existing standards and legal requirements.

Or. en

Amendment 239
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 59 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.	4. Member States shall ensure that national competent authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation. In particular, national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data ***protection*** and data computing, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements.

Or. en

Amendment 240
Margrete Auken
on behalf of the Greens/EFA Group

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 intended to protect fundamental ***or legal*** rights to the market surveillance authorities of the Member States where that incident or breach occurred.

Or. en

Amendment 241
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 62 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Upon receiving a notification related to a breach of obligations under Union law intended to protect fundamental rights, the market surveillance authority shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued 12 months after the entry into force of this Regulation, at the latest.	2. Upon receiving a notification related to a breach of obligations under Union law intended to protect fundamental ***or legal*** rights, the market surveillance authority shall inform ***the individuals who have been affected and*** 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 242
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 64 – paragraph 3

Text proposed by the Commission	*Amendment*
3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market	3. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental ***and legal*** rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the market

surveillance authority of the Member State concerned of any such request.	surveillance authority of the Member State concerned of any such request.

Or. en

Amendment 243
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 65 – paragraph 1

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

Or. en

Amendment 244
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 65 – paragraph 1

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

Or. en

Amendment 245
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 65 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. Where the protection of fundamental rights or public interest is at risk, Member States need to ensure procedures for civil society organisations and other stakeholders to be able to submit input and lodge complaints to the market surveillance authority of a Member State or to the national public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III.

Or. en

Amendment 246
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 65 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall cooperate as necessary with the market surveillance authorities and the other national public	2. Where the market surveillance authority of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to the protection of fundamental rights are present, the market surveillance authority ***ex-officio or following a complaint by civil society organisations or other stakeholders*** shall also inform the relevant national public authorities or bodies referred to in Article 64(3). The relevant operators shall

authorities or bodies referred to in Article 64(3).	cooperate as necessary with the market surveillance authorities and the other national public authorities or bodies referred to in Article 64(3).

Or. en

Amendment 247
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 67 – paragraph 1

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

Or. en

Amendment 248
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 249
César Luena, Javi López, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Article 68 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the conformity marking has not been affixed;	(b) the conformity ***marking or the energy efficiency and carbon intensity*** marking has not been affixed;

Or. en

Amendment 250
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 69 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission and the Board	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.	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 ***a European code for data centre energy efficiency should contain key sustainability indictors related*** to environmental sustainability***, resource usage and energy efficiency, the proportion of energy generated from renewable energy sources and reuse of any heat or waste***, 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.

Or. en

Amendment 251
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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***, energy efficiency and carbon intensity***, 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.

Or. en

Amendment 252
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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), 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].	2. The delegation of power referred to in Article 7(1), Article 11(3), Article 43(5) and (6)**,**Article 48(5) ***and Article 49a(3)*** shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].

Or. en

Amendment 253
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 7(1), Article 11(3), Article 43(5) and (6)**,** Article 48(5) ***and Article 49a(3)*** 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

Amendment 254
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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 7(1), Article 11(3), Article 43(5) and (6)***,*** Article 48(5) ***and Article 49a(3)*** 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

Amendment 255
Margrete Auken
on behalf of the Greens/EFA Group

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

Text proposed by the Commission	*Amendment*
	3 a. Within [two years after the date of application of this Regulation referred to in Article 85(2)] and every two years thereafter, the Commission shall evaluate the environmental impact and effectiveness of this Regulation with regards to energy use and/or other environmental impact of AI systems and bring forward a proposal to regulate the energy efficiency to ensure the full decarbonisation of AI technologies by January 2050.

Or. en

Amendment 256

Michal Wiezik

Proposal for a regulation
Annex I – point a

Text proposed by the Commission	*Amendment*
(a) Machine learning approaches, including supervised, unsupervised ***and*** reinforcement learning, using a wide variety of methods including deep learning;	(a) Machine learning approaches, including supervised, unsupervised***,*** reinforcement learning ***and computational scientific discovery***, using a wide variety of methods including deep learning;

Or. en

Amendment 257
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex III – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Environmental impact and energy use:
	(a) AI systems that require a higher frequency of training and re-training of models than 60% of comparable state-of-the-art systems;
	(b) AI systems that require training or re-training of data quantities that exceed 60% of comparable state-of-the-art systems;
	(c) AI systems that require the re-training of partial data-sets involved where these exceed 20% of the data globally available to the system;
	(d) AI systems other than those which make use of techniques involving the training of models that are resource intensive than 60% of the comparable state-of-the-art systems

Or. en

Amendment 258
Marie Toussaint, David Cormand

Proposal for a regulation
Annex III – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Environmental impact and energy use:
	According to the "proportionality framework" assessing whether the training or the tuning of an AI model for a particular task is proportional to the carbon footprint and environmental impact it would have:
	(a) AI systems whose predicted environmental costs exceed the social, environmental and economic demonstrated benefit; or
	(b) AI systems where another non-AI solution with an equivalent level of success is available.

Or. en

Amendment 259
Joanna Kopcińska

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;	(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, ***including healthcare service and health literacy*** as well as to grant, reduce, revoke, or reclaim such benefits and services;

Or. en

Amendment 260
César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

Proposal for a regulation
Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	8 a. Health, health care, long-term care and health insurance:
	(a) AI systems not covered by Regulation (EU) 2017/745 intended to be used in the health, health care and long-term care sectors that have indirect and direct effects on health or that use sensitive health data.
	(b) AI administrative and management systems used by healthcare professionals in hospitals and other healthcare settings and by health insurance companies that process sensitive data of people's health.

Or. en

Justification

The proposal assumes that all AI applications used in the context of health are covered by Regulation (EU) 2017/745. However, this Regulation only covers medical devices and software with an intended medical purpose, such as treatment of patients. This excludes health related AI applications (for example, apps to track medication) and administrative AI systems used by doctors in a hospital or other healthcare setting that still present new challenges and possible risks to people, because of their effects on health or the use of sensitive health data and life choices.

Amendment 261
Marie Toussaint, David Cormand

Proposal for a regulation
Annex III a (new)

Text proposed by the Commission	*Amendment*
	ANNEX IIIa - ENVIRONMENTAL IMPACT INFORMATION referred to in Article 10a

1. Measurements:

For the purposes of measuring energy consumption and/or any other environmental impact of AI systems', accurate, reliable and reproducible measurements shall take into account recognised state-of-the-art measurement methods or new quantitative systems of measurement that enable the comparison of the environmental impact of the systems used. These measurements shall take the form of a multicriteria life cycle assessment.

The measurements shall:

(a) record the ambient temperature at the time of each measurement;

(b) include the corresponding process or state the system is in;

(c) include the volume and type of data processed and stored;

(d) document the technical equipment used;

(e) take account of the material resource and energy consumption, the amount of heat, electric and electronic waste generated

(f) include a quantitative assessment of how the system affects environmental parameters, including climate change mitigation and adaption, including greenhouse gas emissions that result from the AI system.

2. The environmental impact information should include a description of the provider's best effort to render his or her AI system environmentally performant, notably with regard to resource use and data minimisation.

Or. en

Amendment 262
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex III a (new)

Text proposed by the Commission	*Amendment*
	ANNEX IIIa - ENVIRONMENTAL IMPACT INFORMATION referred to in Article 10a
	1. Measurements:
	For the purposes of measuring greenhouse gas emissions, energy consumption and/or any other environmental impact of AI systems', accurate, reliable and reproducible measurements shall take into account recognised state-of-the-art measurement methods or new quantitative systems of measurement that enable the comparison of the environmental impact of the systems used.
	The measurements shall:
	(a) record the computing power required for training, fine-tuning and use;
	(b) record the type, time and location of computing infrastructure used;
	(c) include specific information the model architecture, volume and type of data used and stored;
	(d) document the technical equipment used and frequency of training, re-training and fine-tuning;
	(e) take account of the energy consumption, the amount of heat, electric and electronic waste generated
	(f) include a quantitative assessment of how the system affects climate change mitigation and adaption, including greenhouse gas emissions that result from the AI system.

Or. en

Amendment 263

César Luena, Javi López, Estrella Durá Ferrandis, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
(g) instructions of use for the user and, where applicable installation instructions;	(g) ***clear and concise*** instructions of use for the user ***including in relation to possible risks to fundamental rights and discrimination*** and, where applicable installation instructions;

Or. en

Amendment 264
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex IV – paragraph 1 – point 2 – point g a (new)

Text proposed by the Commission	*Amendment*
	(g a) the computational complexity of the system and its software components, its data use, including the validation and testing of systems.

Or. en

Amendment 265
Margrete Auken
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex IV – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance***, environmental sustainability and energy efficiency***, including the degrees of

which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;	accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to ***climate and environmental protection,*** health and safety, fundamental ***or legal*** rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

Or. en

Amendment 266
Stelios Kympouropoulos

Proposal for a regulation
Annex IV – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;	3. Detailed information ***and fully accessible*** about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

Or. en

Amendment 267
Deirdre Clune

Proposal for a regulation
Annex IV – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;	3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to ***the environment,*** health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

Or. en

Amendment 268
César Luena, Javi López, Cyrus Engerer, Milan Brglez

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

Text proposed by the Commission	*Amendment*
	3 a. Detailed information about the carbon footprint and the energy efficiency of the AI system, in particular with regard to the development of hardware and algorithm design and training processes,

and the systematic analysis of the energy consumption of the applications being run.

Or. en