



2021/0106(COD)

12.9.2022

OPINION

of the Committee on Legal Affairs

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

on the proposal for a regulation of the European Parliament and of the Council
laying down harmonised rules on artificial intelligence (Artificial Intelligence
Act) and amending certain Union Legislative Acts
(COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

Rapporteur for opinion: Axel Voss

PA_Legam

AMENDMENTS

The Committee on Legal Affairs calls on the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs, as the committees responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation

Recital 1

Text proposed by the Commission

(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.

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 ***principles and democratic*** 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.

Amendment 2

Proposal for a regulation

Recital 3

Text proposed by the Commission

(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

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 ***if developed in accordance with relevant general principles in line with the EU***

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.

Charter of Fundamental Rights and the values on which the Union is founded. 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.

Amendment 3

Proposal for a regulation

Recital 4

Text proposed by the Commission

(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.

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Amendment 4

Proposal for a regulation

Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) Building on the seven key requirements set out by the High-Level Expert Group on Artificial Intelligence, it is important to note that AI systems should respect general principles

establishing a high-level framework that promotes a coherent human-centric approach to ethical and trustworthy AI in line with the Charter of Fundamental Rights of the European Union and the values on which the Union is founded, including the protection of fundamental rights, human agency and oversight, technical robustness and safety, privacy and data governance, transparency, non-discrimination and fairness and societal and environmental wellbeing.

Amendment 5

Proposal for a regulation Recital 13

Text proposed by the Commission

(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.

Amendment

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety, fundamental rights **and the environment**, common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter), **the European Green Deal (The Green Deal) and the Joint Declaration on Digital Rights of the Union (the Declaration)** and should be non-discriminatory and in line with the Union's international commitments.

Amendment 6

Proposal for a regulation Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) For this Regulation to be effective, it is essential to address the issue of the digital divide and, therefore, it should be

accompanied by a policy of education, training and awareness as regards these technologies that ensures a sufficient level of AI literacy.

Amendment 7

Proposal for a regulation Recital 14 b (new)

Text proposed by the Commission

Amendment

(14b) ‘AI literacy’ refers to skills, knowledge and understanding that allows providers, users and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause and thereby promote its democratic control. AI literacy should not be limited to learning about tools and technologies, but should also aim to equip providers and users with the notions and skills required to ensure compliance with and enforcement of this Regulation. It is therefore necessary that the Commission, the Member States as well as providers and users of AI systems, in cooperation with all relevant stakeholders, promote the development of a sufficient level of AI literacy, in all sectors of society, for citizens of all ages, including women and girls, and that progress in that regard is closely followed.

Amendment 8

Proposal for a regulation Recital 15

Text proposed by the Commission

Amendment

(15) Aside from the many beneficial

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uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.

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Amendment 9

Proposal for a regulation

Recital 16

Text proposed by the Commission

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

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with this Regulation, further flexibilities in order to foster research, and thereby European innovation capacities, should be introduced by Member States.

Amendment 10

Proposal for a regulation

Recital 28

Text proposed by the Commission

(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

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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.

right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration, ***right to protection of intellectual property, cultural diversity***. In addition to those rights, it is important to highlight that children have specific rights as enshrined 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.

Amendment 11

Proposal for a regulation Recital 47 a (new)

Text proposed by the Commission

Amendment

(47a) Such requirements on transparency and on the explicability of AI decision-making should also help to counter the deterrent effects of digital asymmetry and so-called 'dark patterns' targeting individuals and their informed consent.

Amendment 12

Proposal for a regulation Recital 48 a (new)

Text proposed by the Commission

Amendment

(48a) Human oversight aims at serving

human-centric objectives. The individuals to whom human oversight is assigned should be provided with adequate education and training on the functioning of the AI system, its capabilities to influence or make decisions, the possible harmful effects it can cause, notably on fundamental rights, and its probability of occurrence. The persons in charge of the assignment of these individuals should provide them with the necessary staff and psychological support and authority to exercise their function.

Amendment 13

Proposal for a regulation Recital 57 a (new)

Text proposed by the Commission

Amendment

(57a) AI systems, which have been placed on the market but require further training or the use of a model not provided by the provider should be considered as general purpose AI system. The training of these systems after they have been placed in the market should be considered as adapting them to a specific purpose;

Amendment 14

Proposal for a regulation Recital 57 b (new)

Text proposed by the Commission

Amendment

(57b) Open Source software licences allow users to run, copy, distribute, study, change and improve software freely. By default the use of Open Source software in this manner attributes liability to the user, whereas when a provider provides Open Source software commercially under a Software as a Service (SaaS) or

Professional Services model, then the provider may retain the liability instead of the user. Research by the European Commission shows that Open Source software contributes between €65bn - €95bn to the European Union's GDP, and provides significant growth opportunities for the Union economy. Open Source providers should be able to adopt the same economic model for AI systems. Hence, the provisions of this Regulation should not apply to Open Source AI systems until those systems are put into service. To ensure that AI systems cannot be put into service without complying with this Regulation, when an Open Source AI System is put into service, the obligations associated with providers should be transferred to the person putting the system into service.

Amendment 15

Proposal for a regulation Recital 73

Text proposed by the Commission

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

Amendment

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Amendment 16

Proposal for a regulation Recital 76

Text proposed by the Commission

(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.

Amendment

(76) In order to *avoid fragmentation and ensure the optimal functioning of the Single Market, it is essential to guarantee an* effective and harmonised implementation of this Regulation. ***To this end***, a European Artificial Intelligence Board should be established ***and entrusted with*** 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. ***However, such a solution might prove not to be sufficient to ensure a fully coherent cross-border action and, therefore, [within three years after the date of application of this Regulation], the Commission should be required to consider whether the creation of an EU Agency is necessary to ensure a consistent application of this Regulation at Union level.***

Amendment 17

Proposal for a regulation Recital 76 a (new)

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

Amendment 18

Proposal for a regulation

Recital 77

Text proposed by the Commission

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

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into account that, given the current lack of AI experts, it might be difficult to ensure at national level that the supervisory authorities are provided with adequate human resources to perform their tasks, Member States are also strongly encouraged to consider the possibility of creating transnational entities for the purpose of ensuring joint supervision of the implementation of this Regulation.

Amendment 19

Proposal for a regulation Recital 80 a (new)

Text proposed by the Commission

Amendment

(80a) Natural or legal persons affected by decisions made by AI systems which produce legal effects that adversely affect their health, safety, fundamental rights, socio-economic well-being or any other of their rights deriving from the obligations laid down in this Regulation, should be entitled to an explanation of that decision. Such an explanation is to be provided to the affected persons and, therefore, when providing such an explanation, providers and users should duly take into account that the level of expertise and knowledge of the average consumer or citizen regarding AI systems is limited and much lower than the one that they possess. On the other hand, some AI systems cannot provide an explanation for their decisions beyond the initial input data. When AI systems are required to provide an explanation and cannot, they should clearly state that an explanation cannot be provided. This should be taken into account by any administrative, non-administrative or judicial authority dealing with complaints from affected persons.

Amendment 20

Proposal for a regulation Recital 85

Text proposed by the Commission

(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.

Amendment

(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment 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-Making⁵⁸. ***These consultations should involve the participation of a balanced selection of stakeholders, including consumer organisations, associations representing affected persons, business representatives from different sectors and of different sizes, trade unions as well as researchers and scientists.*** In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert

groups dealing with the preparation of delegated acts.

Amendment 21

Proposal for a regulation Recital 86 a (new)

Text proposed by the Commission

Amendment

(86a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the powers delegated to the Commission and the implementing powers conferred on it should be exercised with as much flexibility as possible. The Commission should regularly review Annex III without undue delay while consulting with the relevant stakeholders.

Amendment 22

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

Text proposed by the Commission

Amendment

(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union;

(a) harmonised rules for the ***development***, placing on the market, the putting into service and the use of ***human-centric and trustworthy*** artificial intelligence systems ('AI systems') in the Union ***in compliance with democratic values***;

Amendment 23

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

Text proposed by the Commission

Amendment

(d) harmonised transparency rules for

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AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content;

certain AI systems;

Amendment 24

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

Text proposed by the Commission

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

Amendment

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

Amendment 25

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

Text proposed by the Commission

Amendment

(ea) a high level protection of public interests, such as health, safety, fundamental rights and the environment, against potential harms caused by artificial intelligence;

Amendment 26

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

Text proposed by the Commission

Amendment

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

Amendment 27

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Amendment 28

Proposal for a regulation

Article 2 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

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

Amendment 29

Proposal for a regulation

Article 2 – paragraph 1 – point c

Text proposed by the Commission

Amendment

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

(c) providers and users of AI systems that are located in a third country, where the output, ***meaning predictions, recommendations or decisions*** produced by the system ***and influencing the environment it interacts with***, is used in the Union ***and puts at risk the environment or the health, safety or fundamental rights of natural persons physically present in the Union, insofar as the provider or user has permitted, is aware or can reasonably expect such a use***;

Amendment 30

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ca) importers, distributors, and authorised representatives of providers of AI systems;

Amendment 31

Proposal for a regulation

Article 2 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

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

- (a) Regulation (EC) 300/2008;**
- (b) Regulation (EU) No 167/2013;**
- (c) Regulation (EU) No 168/2013;**
- (d) Directive 2014/90/EU;**
- (e) Directive (EU) 2016/797;**
- (f) Regulation (EU) 2018/858;**
- (g) Regulation (EU) 2018/1139;**
- (h) Regulation (EU) 2019/2144.**

2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems **and that fall** within the scope of the **listed acts in Annex II, section B**, only Article 84 of this Regulation shall apply.

Amendment 32

Proposal for a regulation

Article 2 – paragraph 3

Text proposed by the Commission

Amendment

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

deleted

Amendment 33

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

Text proposed by the Commission

Amendment

3a. This Regulation shall not affect research, testing and development activities regarding an AI system prior to this system being placed on the market or put into service, provided that these activities are conducted respecting fundamental rights and the applicable Union law. The Commission is empowered to adopt delegated acts in accordance with Article 73 to specify this exemption. The Board shall provide guidance on the governance of research and development pursuant to Article 56 (2) (cc), also aiming at coordinating the way this exemption is put in place by the Commission and the national supervisory authorities.

Amendment 34

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

Text proposed by the Commission

Amendment

3b. Title III of this Regulation shall not apply to AI systems that are used in a strictly business-to-business environment and provided that those systems do not pose a risk of harm to the environment, health or safety or a risk of adverse impact on fundamental rights.

Amendment 35

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

Text proposed by the Commission

Amendment

4a. *This regulation shall not apply to Open Source AI systems until those systems are put into service or made available on the market in return for payment, regardless of if that payment is for the AI system itself, the provision of the AI system as a service, or the provision of technical support for the AI system as a service.*

Amendment 36

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

Text proposed by the Commission

Amendment

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

Amendment 37

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

Text proposed by the Commission

Amendment

(1b) *‘open source AI systems’ means AI systems, including test and training data, or trained models, distributed under open licenses.*

Amendment 38

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

Text proposed by the Commission

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

Amendment

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

Amendment 39

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

Text proposed by the Commission

Amendment

(4a) ‘affected person’ means any natural person or a group of persons who are subject to or affected by an AI system

Amendment 40

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

Text proposed by the Commission

Amendment

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

deleted

Amendment 41

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

Text proposed by the Commission

Amendment

(44a) 'AI literacy' means the skills, knowledge and understanding regarding AI systems that are necessary for the compliance with and enforcement of this Regulation.

Amendment 42

Proposal for a regulation Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4a

General principles applicable to all AI systems

1. All AI operators shall respect the following general principles that establish a high-level framework that promotes a coherent human-centric European approach to ethical and trustworthy Artificial Intelligence, which is fully in line with the Charter as well as the values on which the Union is founded:

- 'human agency and oversight' means that AI systems shall be developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be appropriately controlled and overseen by humans.***
- 'technical robustness and safety' means that AI systems shall be developed and used in a way to minimize unintended and unexpected harm as well as being robust in case of unintended problems and being resilient against attempts to alter the use or performance of the AI system so as to allow unlawful use by malicious third parties.***
- 'privacy and data governance' means that AI systems shall be developed and***

used in compliance with existing privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity.

- *‘transparency’ means that AI systems shall be developed and used in a way that allows appropriate traceability and explainability, while making humans aware that they communicate or interact with an AI system as well as duly informing users of the capabilities and limitations of that AI system and affected persons about their rights.*

- *‘diversity, non-discrimination and fairness’ means that AI systems shall be developed and used in a way that includes diverse actors and promotes equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national law.*

- *‘social and environmental well-being’ means that AI systems shall be developed and used in a sustainable and environmentally friendly manner as well as in a way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy.*

2. Paragraph 1 is without prejudice to obligations set up by existing Union and national law.

For high-risk AI systems, the general principles are translated into and complied with by providers or users by means of the requirements set out in Articles 8 to 15 of this Regulation. For all other AI systems, the voluntary application on the basis of harmonised standards, technical specifications and codes of conduct as referred to in Article 69 is strongly encouraged with a view to fulfilling the principles listed in paragraph 1.

3. The Commission and the Board shall issue recommendations that help

guiding providers and users on how to develop and use AI systems in accordance with the general principles. European Standardisation Organisations shall take the general principles referred to in paragraph 1 into account as outcome-based objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b).

Amendment 43

Proposal for a regulation Article 4 b (new)

Text proposed by the Commission

Amendment

Article 4b

AI literacy

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

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

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

4. *A sufficient level of AI literacy is one that contributes, as necessary, to the ability of providers and users to ensure compliance and enforcement of this Regulation.*

Amendment 44

Proposal for a regulation

Article 9 – paragraph 4 - subparagraph 2 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, **where appropriate**, training to users.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and training to users, **as appropriate to ensure a sufficient level of AI literacy in line with Article 4b.**

Amendment 45

Proposal for a regulation

Article 9 – paragraph 9

Text proposed by the Commission

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

Amendment

9. For **providers of AI systems already covered by other acts of Union law that require them to put in place specific risk management systems, including** credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those **acts of Union law.**

Amendment 46

Proposal for a regulation Article 13 – title

Text proposed by the Commission

Transparency and provision of information
to users

Amendment

Transparency and provision of information

Amendment 47

Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

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

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable *providers and* users to *reasonably understand* the system's *functioning*. Appropriate transparency shall be ensured *in accordance with the intended purpose of the AI system*, with a view to achieving compliance with the relevant obligations of the provider *and user* set out in Chapter 3 of this Title.

Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall be enabled to understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, allowing the user to explain the decisions taken by the AI system to the affected person pursuant to Article 68(c).

Amendment 48

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission

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

Amendment

2. High-risk AI systems shall be accompanied by **intelligible** instructions for use in an appropriate digital format or **made** otherwise **available in a durable medium** that include concise, **correct, clear and to the extent possible** complete information that **helps operating and maintaining the AI system as well as supporting informed decision-making by users and is reasonably** relevant, accessible and comprehensible to users .

Amendment 49

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

Text proposed by the Commission

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

Amendment

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

Amendment 50

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

Text proposed by the Commission

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

Amendment

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

Amendment 51

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

Text proposed by the Commission

Amendment

(aa) *where it is not the same as the provider, the identity and the contact details of the entity that carried out the conformity assessment and, where applicable, of its authorised representative;*

Amendment 52

Proposal for a regulation

Article 13 – paragraph 3 – point b – introductory part

Text proposed by the Commission

Amendment

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

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

Amendment 53

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

Amendment

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

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

Amendment 54

Proposal for a regulation

Article 13 – paragraph 3 – point b – point iii

Text proposed by the Commission

Amendment

(iii) any known or foreseeable

(iii) any ***clearly*** 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;

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

Amendment 55

Proposal for a regulation

Article 13 – paragraph 3 – point b – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) the degree to which the AI system can provide an explanation for decisions it takes;

Amendment 56

Proposal for a regulation

Article 13 – paragraph 3 – point b – point v

Text proposed by the Commission

Amendment

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

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

Amendment 57

Proposal for a regulation

Article 13 – paragraph 3 – point e

Text proposed by the Commission

(e) ***the expected lifetime of the high-risk AI system and*** any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.

Amendment

(e) any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates, ***through its expected lifetime.***

Amendment 58

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ea) a description of the mechanisms included within the AI system that allows users to properly collect, store and interpret the logs in accordance with Article 12(1).

Amendment 59

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(eb) The information shall be provided at least in the language of the country where the AI system is used.

Amendment 60

Proposal for a regulation

Article 13 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In order to comply with the obligations laid down in this Article, providers and users shall ensure a sufficient level of AI literacy in line with Article 4b.

Amendment 61

Proposal for a regulation Article 14 – paragraph 1

Text proposed by the Commission

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

Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they be effectively overseen by natural persons **as proportionate to the risks associated with those systems. Natural persons in charge of ensuring human oversight shall have sufficient level of AI literacy in accordance with Article 4b and the necessary support and authority to exercise that function**, during the period in which the AI system is in use **and to allow for thorough investigation after an incident**.

Amendment 62

Proposal for a regulation Article 14 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Amendment 63

Proposal for a regulation

Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

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

Amendment

3. Human oversight ***shall take into account the specific risks, the level of automation, and context of the AI system and*** shall be ensured through either one or all of the following ***types of*** measures:

Amendment 64

Proposal for a regulation

Article 14 – paragraph 4 – introductory part

Text proposed by the Commission

4. ***The measures referred to in paragraph 3*** shall ***enable the individuals*** to whom human oversight is assigned ***to do the following***, as appropriate to the circumstances:

Amendment

4. ***For the purpose of implementing paragraphs 1 to 3, the high-risk AI system shall be provided to the user in such a way that natural persons*** to whom human oversight is assigned ***are enabled***, as appropriate ***and proportionate*** to the circumstances:

Amendment 65

Proposal for a regulation

Article 14 – paragraph 4 – point a

Text proposed by the Commission

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

Amendment

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

Amendment 66

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

Text proposed by the Commission

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

Amendment

(e) be able to intervene on the operation of the high-risk AI system or interrupt, the system through a “stop” button or a similar procedure ***that allows the system to come to a halt in a safe state, except if the human interference increases the risks or would negatively impact the performance in consideration of generally acknowledged state-of-the-art.***

Amendment 67

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

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

Amendment

5. For high-risk AI systems referred to in point1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons ***with the necessary competence, training and authority.***

Amendment 68

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

Text proposed by the Commission

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

Amendment

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

Title;

Title, *before placing them on the market or putting them into service*;

Amendment 69

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

Text proposed by the Commission

Amendment

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

Amendment 70

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

Text proposed by the Commission

Amendment

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

(c) *keep the documentation and, where not yet available, draw up* the technical documentation *referred to in Article 18*;

Amendment 71

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

Text proposed by the Commission

Amendment

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

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

Amendment 72

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

Text proposed by the Commission

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

Amendment

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

Amendment 73

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

Text proposed by the Commission

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

Amendment

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

Amendment 74

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

Text proposed by the Commission

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

Amendment

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

Amendment 75

Proposal for a regulation
Article 23 a (new)

Text proposed by the Commission

Amendment

Article 23a

Conditions for other persons to be subject to the obligations of a provider

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

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

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

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

(d) they place on the market or make available on the market, with or without modification and in return for payment an Open Source AI system, an AI system derived from an Open Source AI system, or Technical Support Services for any such Open Source AI systems;

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

2. Where the circumstances referred to in paragraph 1, points (a), (b), (c) or (d), occur, the former provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation. The former provider shall upon request and respecting its own intellectual property rights or trade secrets, provide the new provider with all essential, relevant and

reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

3. The original provider of a general purpose AI system as referred to in paragraph 1, point (e), shall, respecting its own intellectual property rights or trade secrets and taking into account the risks that are specifically linked to the adaption of the general purpose AI system to a specific intended purpose:

(a) ensure that the general purpose AI system which may be used as high-risk AI system complies with the requirements established in Articles 9, 10, 11, 13(2) and (3), 14(1) and 15 of this Regulation;

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

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

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

4. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations referred to in Article 16 under either of the following scenarios:

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

(ii) the high-risk AI system is put into service under the name or trademark of

the product manufacturer after the product has been placed on the market.

5. Third parties involved in the sale and the supply of software including general purpose application programming interfaces (API), software tools and components, or providers of network services shall not be considered providers for the purposes of this Regulation.

Amendment 76

Proposal for a regulation Article 29 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Users of high-risk AI systems shall **take appropriate organisational measures and ensure that the use of** such systems **takes place** in accordance with the instructions of use accompanying the systems pursuant to paragraphs **1a to 5 of this Article**. **Users shall bear responsibility in case of any use of the AI system that is not in accordance with the instructions of use accompanying the systems.**

Amendment 77

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

Text proposed by the Commission

Amendment

1a. To the extent the user exercises control over the high-risk AI system, that user shall assign human oversight to natural persons who have the necessary AI literacy in accordance with Article 4b.

Amendment 78

Proposal for a regulation Article 29 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Amendment 79

Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Amendment 80

Proposal for a regulation
Article 29 – paragraph 4 – subparagraph 1

Text proposed by the Commission

4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident or **any** malfunctioning **within the meaning of Article 62** and interrupt the use

Amendment

4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use **and, when relevant, inform the provider in accordance with Article 61. To the extent the user exercises control over the high-risk AI system, it shall also perform a risk assessment in accordance with Article 9 but limited to the potential adverse effects of using the high-risk AI system as well as the respective mitigation measures.** When they have reasons to consider that the use in accordance with the instructions of use

of the AI system. In case the user is not able to reach the provider, Article 62 shall apply *mutatis mutandis*.

may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor ***and competent supervisory authority*** when they have identified any serious incident or malfunctioning and interrupt the use of the AI system. In case the user is not able to reach the provider ***importer or distributor***, Article 62 shall apply *mutatis mutandis*.

Amendment 81

Proposal for a regulation

Article 29 – paragraph 5 – subparagraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 82

Proposal for a regulation

Article 29 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Amendment 83

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

Text proposed by the Commission

Amendment

6a. The provider shall be obliged to cooperate closely with the user and in particular provide the user with the necessary and appropriate information to allow the fulfilment of the obligations set out in this Article.

Amendment 84

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

Text proposed by the Commission

Amendment

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

Amendment 85

Proposal for a regulation Article 40 – paragraph 1

Text proposed by the Commission

Amendment

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

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

Amendment 86

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

Text proposed by the Commission

Amendment

1a. When issuing a standardisation request to European standardisation organisations in accordance with Article 10 of Regulation (EU)1025/2012, the Commission shall specify that standards are coherent, easy to implement and drafted in such a way that they aim to fulfil in particular the following objectives:

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

b) take into account the general principles for trustworthy AI set out in Article 4a;

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

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

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

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

1b. The Commission shall issue standardisation requests covering all requirements of this Regulation in accordance with Article 10 of Regulation (EU) No1025/2012 before the date of entry into force of this Regulation.

Amendment 87

Proposal for a regulation Article 52 – title

Text proposed by the Commission

Transparency obligations *for certain AI systems*

Amendment

Transparency obligations

Amendment 88

Proposal for a regulation Article 52 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that ***the AI system, the provider itself or the user informs the natural person exposed to an AI system*** that they are interacting with an AI system ***in a timely, clear and intelligible manner***, unless this is obvious from the circumstances and the context of use.

Where appropriate and relevant, this information shall also include which functions are AI enabled, if there is human oversight, and who is responsible for the decision-making process, as well as the existing rights and processes that, according to Union and national law, allow natural persons or their representatives to object against the application of such systems to them and to seek judicial redress against decisions taken by or harm caused by AI systems, including their right to seek an explanation. This obligation shall not apply to AI systems authorised by law to

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

Amendment 89

Proposal for a regulation Article 52 – paragraph 2

Text proposed by the Commission

2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.

Amendment

2. Users of an emotion recognition system or a biometric categorisation system ***which is not prohibited pursuant to Article 5*** shall inform ***in a timely, clear and intelligible manner*** of the operation of the system the natural persons exposed thereto ***and obtain their consent prior to the processing of their biometric and other personal data in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable***. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.

Amendment 90

Proposal for a regulation Article 52 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Amendment

3. Users of an AI system that generates or manipulates ***text***, audio or ***visual*** content that would falsely appear to be authentic or truthful ***and which features depictions of people appearing to say or do things they did not say or do, without their consent*** ('deep fake'), shall disclose ***in an appropriate, timely, clear and visible manner*** that the content has been artificially generated or manipulated, ***as***

well as, whenever possible, the name of the natural or legal person that generated or manipulated it. Disclosure shall mean labelling the content in a way that informs that the content is inauthentic and that is clearly visible for the recipient of that content. To label the content, users shall take into account the generally acknowledged state of the art and relevant harmonised standards and specifications.

Amendment 91

Proposal for a regulation Article 52 – paragraph 3 – subparagraph 2

Text proposed by the Commission

However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.

Amendment

3a. *Paragraph 3 shall not apply where the use of an AI system that generates or manipulates text, audio or visual content is authorized by law or if it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties. Where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video games visuals and analogous work or programme, transparency obligations set out in paragraph 3 are limited to disclosing of the existence of such generated or manipulated content in an appropriate clear and visible manner that does not hamper the display of the work and disclosing the applicable copyrights, where relevant. It shall also not prevent law enforcement authorities from using AI systems intended to detect deep fakes and prevent, investigate and prosecute criminal offences linked with their use*

Amendment 92

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

Text proposed by the Commission

Amendment

3b. *The information referred to in paragraphs 1 to 3 shall be provided to the natural persons at the latest at the time of the first interaction or exposure. It shall be accessible to vulnerable persons, such as persons with disabilities or children, complete, where relevant and appropriate, with intervention or flagging procedures for the exposed natural person taking into account the generally acknowledged state of the art and relevant harmonised standards and common specifications.*

Amendment 93

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission

Amendment

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established.

1. A ‘European Artificial Intelligence Board’ (the ‘Board’) is established ***as an independent body with its own legal personality to promote a trustworthy, effective and competitive internal market for artificial intelligence. The Board shall be organised in a way that guarantees the independence, objectivity and impartiality of its activities and shall have a secretariat, a strong mandate as well as sufficient resources and skilled personnel at its disposal for assistance in the proper performance of its tasks laid down in Article 58.***

Amendment 94

Proposal for a regulation
Article 56 – paragraph 2 – introductory part

Text proposed by the Commission

2. The Board shall provide advice and assistance to the Commission in order to:

Amendment

2. The Board shall provide advice and assistance to the Commission **and the Member States, when implementing Union law related to artificial intelligence as well as cooperate with the providers and users of AI systems** in order to:

Amendment 95

Proposal for a regulation

Article 56 – paragraph 2 – point a

Text proposed by the Commission

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

Amendment

(a) **promote and support** the effective cooperation of the national supervisory authorities and the Commission;

Amendment 96

Proposal for a regulation

Article 56 – paragraph 2 – point c

Text proposed by the Commission

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

Amendment

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

Amendment 97

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ca) **assist providers and users of AI**

systems to meet the requirements of this Regulation, as well as those set out in present and future Union legislation, in particular SMEs and start-ups.

Amendment 98

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

Text proposed by the Commission

Amendment

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

Amendment 99

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

Text proposed by the Commission

Amendment

(cc) propose amendments to Annex I and III.

Amendment 100

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

Text proposed by the Commission

Amendment

2a. The Board shall act as a reference point for advice and expertise for Union institutions, bodies, offices and agencies as well as for other relevant stakeholders on matters related to artificial intelligence.

Amendment 101

Proposal for a regulation Article 57 – title

Text proposed by the Commission

Structure of the Board

Amendment

Mandate and structure of the Board

Amendment 102

Proposal for a regulation Article 57 – paragraph 1

Text proposed by the Commission

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.

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. Other national authorities may be invited to the meetings, where the issues discussed are of relevance for them. ***The Board composition shall be gender balanced.***

The European Data Protection Supervisor, the Chairperson of the EU Agency for Fundamental Rights, the Executive director of the EU Agency for Cybersecurity, the Chair of the High Level Expert Group on AI, the Director-General of the Joint Research Centre, and the presidents of the European Committee for Standardization, the European Committee for Electrotechnical Standardization, and the European Telecommunications Standards Institute shall be invited as permanent observers with the right to speak but without voting rights.

Amendment 103

Proposal for a regulation Article 57 – paragraph 2

Text proposed by the Commission

2. The Board shall adopt its rules of procedure by a simple majority of its members, ***following the consent of the Commission***. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish sub-groups as appropriate for the purpose of examining specific questions.

Amendment

2. The Board shall adopt its rules of procedure by a simple majority of its members ***with the assistance of its secretariat***. The rules of procedure shall also contain the operational aspects related to the execution of the Board's tasks as listed in Article 58. The Board may establish ***standing or temporary*** sub-groups as appropriate for the purpose of examining specific questions.

Amendment 104

**Proposal for a regulation
Article 57 – paragraph 3**

Text proposed by the Commission

3. The Board shall be ***chaired*** by the Commission. ***The Commission*** shall convene the meetings and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure. The ***Commission*** shall provide administrative and analytical support for the activities of the Board pursuant to this Regulation.

Amendment

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

Amendment 105

**Proposal for a regulation
Article 57 – paragraph 4**

Text proposed by the Commission

4. The Board ***may*** invite external experts ***and observers*** to attend its meetings ***and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that***

Amendment

4. The Board ***shall regularly*** invite external experts, ***in particular from organisations representing the interests of the providers and users of AI systems, SMEs and start-ups, civil society***

end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

organisations, trade unions, representatives of affected persons, academia and researchers, testing and experimentation facilities and standardisation organisations, to attend its meetings in order to ensure accountability and appropriate participation of external actors. The agenda and the minutes of its meetings shall be published online. The Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.

Amendment 106

Proposal for a regulation Article 57 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Without prejudice to paragraph 4, the Board’s Secretariat shall organise four additional meetings between the Board and the High Level Expert Group on Trustworthy AI to allow them to share their practical and technical expertise every quarter of the year.

Amendment 107

Proposal for a regulation Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

When providing advice and assistance to the Commission in the context of Article 56(2), the Board shall in particular:

When providing advice and assistance to the Commission **and the Member States** in the context of Article 56(2), the Board shall in particular:

Amendment 108

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 expertise and best practices among Member States, ***including on the promotion of AI literacy and awareness raising initiatives on Artificial Intelligence and this Regulation;***

Amendment 109

Proposal for a regulation

Article 58 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) promote and support the cooperation among national supervisory authorities and the Commission;

Amendment 110

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) contribute to uniform administrative practices in the Member States, including for the functioning of regulatory sandboxes referred to in Article 53;

(b) contribute to uniform administrative practices in the Member States, including for the ***assessment, establishing, managing with the meaning of fostering cooperation and guaranteeing consistency among regulatory sandboxes, and*** functioning of regulatory sandboxes referred to in Article 53;

Amendment 111

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

(c) issue ***guidelines***, recommendations or written contributions on matters related

to the implementation of this Regulation, in particular

to the implementation of this Regulation, in particular

Amendment 112

Proposal for a regulation

Article 58 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission

Amendment

(iia) on the provisions related to post market monitoring as referred to in Article 61,

Amendment 113

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) on the need for the amendment of each of the Annexes as referred to in Article 73, as well as all other provisions in this Regulation that the Commission can amend, in light of the available evidence.

Amendment 114

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii b (new)

Text proposed by the Commission

Amendment

(iiib) on activities and decisions of Member States regarding post-market monitoring, information sharing, market surveillance referred to in Title VIII;

Amendment 115

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii c (new)

Text proposed by the Commission

Amendment

(iiic) on common criteria for market operators and competent authorities having the same understanding of concepts such as the 'generally acknowledged state of the art' referred to in Articles 9(3), 13(1), 14(4), 23a(3) or 52(3a), 'foreseeable risks' referred to in Articles 9(2), point (a), and 'foreseeable misuse' referred to in Article 3(13), Article 9(2), point (b), Article 9(4), Article 13(3), point (b)(iii), Article 14(2) and Article 23a(3c);

Amendment 116

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii d (new)

Text proposed by the Commission

Amendment

(iiid) on the verification of the alignment with the legal acts listed in Annex II, including with the implementation matters related to those acts.

Amendment 117

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii e (new)

Text proposed by the Commission

Amendment

(iiie) on the respect of the general principles applicable to all AI systems referred to in Article 4a;

Amendment 118

Proposal for a regulation

Article 58 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) carry out annual reviews and analyses of the complaints sent to and findings made by national supervisory authorities, of the serious incidents and malfunctioning reports referred to in Article 62, and of the new registration in the EU Database referred to in Article 60 to identify trends and potential emerging issues threatening the future health and safety and fundamental rights of citizens that are not adequately addressed by this Regulation;

Amendment 119

**Proposal for a regulation
Article 58 – paragraph 1 – point c b (new)**

Text proposed by the Commission

Amendment

(cb) carry out biannual horizontal scanning and foresight exercises to extrapolate the impact that scientific developments, trends and emerging issues can have on the Union;

Amendment 120

**Proposal for a regulation
Article 58 – paragraph 1 – point c c (new)**

Text proposed by the Commission

Amendment

(cc) annually publish recommendations to the Commission, in particular on the categorisation of prohibited practices, high-risk systems, and codes of conduct for AI systems that are not classified as high-risk;

Amendment 121

Proposal for a regulation
Article 58 – paragraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(cd) encourage and facilitate the drawing up of codes of conduct as referred to in Article 69;

Amendment 122

Proposal for a regulation
Article 58 – paragraph 1 – point c e (new)

Text proposed by the Commission

Amendment

(ce) coordinate among national competent authorities and make sure that the consistency mechanism in Article 59a(3) is observed, in particular for all major cross-border cases;

Amendment 123

Proposal for a regulation
Article 58 – paragraph 1 – point c f (new)

Text proposed by the Commission

Amendment

(cf) adopt binding decisions for national supervisory authorities in case the consistency mechanism is not able to solve the conflict among national supervisory authorities as it is clarified in Article 59a (6).

Amendment 124

Proposal for a regulation
Article 58 – paragraph 1 – point c g (new)

Text proposed by the Commission

Amendment

(cg) provide guidance material to providers and users regarding the

compliance with the requirements set out in this Regulation. In particular, it shall issue guidelines:

- i) for the trustworthy AI technical assessment referred to in Article 4a,*
- ii) for the methods for performing the conformity assessment based on internal control referred to Article 43;*
- iii) to facilitate compliance with the reporting of serious incidents or malfunctioning referred to in Article 62;*
- iv) on any other concrete procedures to be performed by providers and users when complying with this Regulation, in particular those regarding the documentation to be delivered to notified bodies and methods to provide authorities with other relevant information.*

Amendment 125

Proposal for a regulation Article 58 – paragraph 1 – point c h (new)

Text proposed by the Commission

Amendment

(ch) provide specific guidance to support SMEs and start-ups in complying with the obligations set out in this Regulation;

Amendment 126

Proposal for a regulation Article 58 – paragraph 1 – point c i (new)

Text proposed by the Commission

Amendment

(ci) raise awareness and provide guidance material to providers and users regarding the compliance with the requirement to put in place tools and measures to ensure a sufficient level of AI literacy in line with Article 4b;

Amendment 127

Proposal for a regulation Article 58 – paragraph 1 – point c j (new)

Text proposed by the Commission

Amendment

(cj) contribute to the Union efforts to cooperate with third countries and international organisations in view of promoting a common global approach towards trustworthy AI;

Amendment 128

Proposal for a regulation Article 58 – paragraph 1 – point c k (new)

Text proposed by the Commission

Amendment

(ck) issue yearly reports on the implementation of this Regulation, including an assessment of its impact on economic operators;

Amendment 129

Proposal for a regulation Article 58 – paragraph 1 – point c l (new)

Text proposed by the Commission

Amendment

(cl) provide guidance on the governance of research and development.

Amendment 130

Proposal for a regulation Article 59 – title

Text proposed by the Commission

Amendment

Designation of national ***competent***

Designation of national ***supervisory***

authorities

authorities

Amendment 131

Proposal for a regulation Article 59 – paragraph 1

Text proposed by the Commission

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.***

Amendment

1. Each Member State ***shall establish or designate one national supervisory authority, which*** shall be organised so as to safeguard the objectivity and impartiality of ***its*** activities and tasks.

Amendment 132

Proposal for a regulation Article 59 – paragraph 2

Text proposed by the Commission

2. ***Each Member State shall designate a national supervisory authority among the national competent authorities. The national supervisory authority shall act as notifying authority and market surveillance authority unless a Member State has organisational and administrative reasons to designate more than one authority.***

Amendment

2. ***The national supervisory authority shall be in charge to ensure the application and implementation of this Regulation. With regard to high-risk AI systems, related to products to which legal acts listed in Annex II apply, the competent authorities designated under those legal acts shall continue to lead the administrative procedures. However, to the extent a case involves aspects covered by this Regulation, the competent authorities shall be bound by measures issued by the national supervisory authority designated under this Regulation.*** The national supervisory authority shall ***also*** act as notifying authority and market surveillance authority.

Amendment 133

Proposal for a regulation
Article 59 – paragraph 3

Text proposed by the Commission

3. Member States shall inform the Commission of their *designation or designations and, where applicable, the reasons for designating more than one authority*.

Amendment

3. ***The national competent authority in each Member State shall be the lead authority, ensure adequate coordination and act as single point of contact for this Regulation.*** Member States shall inform the Commission of their designations. ***In addition, the central contact point of each Member State should be contactable through electronic communications means.***

Amendment 134

Proposal for a regulation
Article 59 – paragraph 4

Text proposed by the Commission

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

Amendment

4. Member States shall ensure that national ***supervisory authority is*** provided with adequate financial and human resources to fulfil ***its*** tasks under this Regulation. In particular, national ***supervisory*** authorities shall have a sufficient number of permanently available ***personnel***, whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data, ***data protection*** and data computing, ***cybersecurity, competition law***, fundamental rights, health and safety risks ***as well as*** knowledge of existing standards and legal requirements.

Amendment 135

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

Text proposed by the Commission

Amendment

4a. The national competent authority shall satisfy the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive (...) on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148.

Amendment 136

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

Text proposed by the Commission

Amendment

4b. Any information and documentation obtained by the national supervisory authority pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Amendment 137

Proposal for a regulation Article 59 – paragraph 5

Text proposed by the Commission

Amendment

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national **competent authorities** with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

5. Member States shall report to the Commission on an annual basis on the status of the financial and human resources of the national **supervisory authority** with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Amendment 138

Proposal for a regulation
Article 59 – paragraph 6

Text proposed by the Commission

6. The Commission shall facilitate the exchange of experience between national *competent* authorities.

Amendment

6. The Commission **and the Board** shall facilitate the exchange of experience between national *supervisory* authorities.

Amendment 139

Proposal for a regulation
Article 59 – paragraph 7

Text proposed by the Commission

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

Amendment

7. National *supervisory* authorities may provide guidance and advice on the implementation of this Regulation, including to **SMEs and start-ups, as long as it is not in contradiction with the Board's or the Commission's guidance and advice.** Whenever national *supervisory* authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the competent national authorities under that Union legislation shall be consulted as appropriate.

Amendment 140

Proposal for a regulation
Article 59 – paragraph 8

Text proposed by the Commission

8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.

Amendment

8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision **and coordination.**

Amendment 141

**Proposal for a regulation
Article 59 a (new)**

Text proposed by the Commission

Amendment

Article 59a

Consistency mechanism for cross-border cases

- 1. Each national supervisory authority shall perform the tasks assigned to and the exercise of the powers conferred on it in accordance with this Regulation on the territory of its own Member State.***
- 2. In the event of a cross-border case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the provider's or user's place of central administration in the Union is established or where the authorised representative is appointed, shall be competent to act as lead national supervisory authority for a cross-border case that involves an AI-system.***
- 3. In the case referred to in paragraph 2, the national supervisory authorities shall cooperate, exchange all relevant information with each other in due time, provide mutual assistance and execute joint operations. National supervisory authorities shall cooperate in order to reach a consensus.***
- 4. In case of a serious disagreement between two or more national supervisory authorities, the lead national supervisory authority shall notify the Board and communicate without delay all relevant information related to the case to the Board.***
- 5. The Board shall within three months of the notification referred to in paragraph 4, issue a binding decision to the national supervisory authorities.***

Amendment 142

Proposal for a regulation Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Such notification shall be made ***immediately*** after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than ***15 days*** after the ***providers*** becomes aware of the serious incident or of the malfunctioning.

Amendment

Such notification shall be made ***without undue delay*** after the provider has established a causal link between the AI system and the ***serious*** incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than ***72 hours*** after the ***provider*** becomes aware of the serious incident or of the malfunctioning.

Amendment 143

Proposal for a regulation Article 62 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

No report under this Article is required if the serious incident or malfunctioning is also to be reported by providers to comply with obligations laid down by other acts of Union law. In that case, the authorities competent under those acts of Union law shall forward the received report to the national supervisory authority designated under this Regulation.

Amendment 144

Proposal for a regulation Article 69 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI

1. The Commission, ***the Board*** and the Member States shall encourage and facilitate the drawing up of codes of conduct intended, ***including where they***

systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

are drawn up in order to demonstrate how AI systems respect the principles set out in Article 4a and can thereby be considered trustworthy, to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

Amendment 145

Proposal for a regulation Article 69 – paragraph 2

Text proposed by the Commission

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.***

Amendment

2. Codes of *conduct* intended to foster the voluntary *compliance with the principles underpinning trustworthy AI systems, shall, in particular:*

(a) aim for a sufficient level of AI literacy among their staff and other persons dealing with the operation and use of AI systems in order to observe such principles;

(b) assess to what extent their AI systems may affect vulnerable persons or groups of persons, including children, the elderly, migrants and persons with disabilities or whether measures could be put in place in order to increase accessibility, or otherwise support such persons or groups of persons;

(c) consider the way in which the use

of their AI systems may have an impact or can increase diversity, gender balance and equality;

(d) have regard to whether their AI systems can be used in a way that, directly or indirectly, may residually or significantly reinforce existing biases or inequalities;

(e) reflect on the need and relevance of having in place diverse development teams in view of securing an inclusive design of their systems;

(f) give careful consideration to whether their systems can have a negative societal impact, notably concerning political institutions and democratic processes;

(g) evaluate how AI systems can contribute to environmental sustainability and in particular to the Union's commitments under the European Green Deal and the European Declaration on Digital Rights and Principles.

Amendment 146

Proposal for a regulation Article 69 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or by both, including with the involvement of users and any interested stakeholders, ***including scientific researchers***, and their representative ***organisations, in particular trade unions, and consumer*** organisations. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems. ***Providers adopting codes of conduct will designate at least one natural person responsible for internal***

monitoring.

Amendment 147

Proposal for a regulation Article 69 – paragraph 4

Text proposed by the Commission

4. The Commission and the Board shall take into account the specific interests and needs of *the small-scale providers* and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Amendment

4. The Commission and the Board shall take into account the specific interests and needs of *SMEs* and start-ups when encouraging and facilitating the drawing up of codes of conduct.

Amendment 148

Proposal for a regulation Article 69 a (new)

Text proposed by the Commission

Amendment

Article 69a

Right to lodge a complaint before a supervisory authority

1. Without prejudice to any other administrative or judicial remedy, every natural or legal person shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the natural or legal person considers that their health, safety, fundamental rights, their right to an explanation or any other of their rights deriving from the obligations laid down in this Regulation have been breached by the provider or the user of an AI system falling within the scope of this Regulation. Such complaint may be lodged through a representative action for the protection of the collective interests of consumers as provided under Directive (EU) 2020/1828.

2. *Natural or legal persons shall have a right to be heard in the complaint handling procedure and in the context of any investigations conducted by the national supervisory authority as a result of their complaint.*

3. *The national supervisory authority with which the complaint has been lodged shall inform the complainants about the progress and outcome of their complaint. In particular, the national supervisory authority shall take all the necessary actions to follow up on the complaints it receives and, within three months of the reception of a complaint, give the complainant a preliminary response indicating the measures it intends to take and the next steps in the procedure, if any.*

4. *The national supervisory authority shall take a decision on the complaint and inform the complainant on the progress and the outcome of the complaint, including the possibility of a judicial remedy pursuant to Article 68b, without delay and no later than six months after the date on which the complaint was lodged.*

Amendment 149

Proposal for a regulation Article 69 b (new)

Text proposed by the Commission

Amendment

Article 69b

Right to an effective judicial remedy against a national supervisory authority

1. *Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial or non-judicial remedy, including repair, replacement, price reduction, contract termination, reimbursement of the price*

paid or compensation for material and immaterial damages, against a legally binding decision of a national supervisory authority concerning them that infringes their rights.

2. Without prejudice to any other administrative or non-judicial remedy, each affected person shall have the right to an effective judicial remedy where the national supervisory authority does not handle a complaint, does not inform the complainant on the progress or preliminary outcome of the complaint lodged within three months pursuant to Article 68a(3) or does not comply with its obligation to reach a final decision on the complaint within six months pursuant to Article 68a(4) or its obligations under Article 65.

3. Proceedings against a supervisory authority shall be brought before the courts of the Member State where the national supervisory authority is established.

Amendment 150

Proposal for a regulation Article 69 c (new)

Text proposed by the Commission

Amendment

Article 69c

Right to an explanation

1. Any affected persons subject to a decision taken by a provider or an user, on the basis of an output from an AI system falling within the scope of this Regulation, which produces legal effects that they consider to adversely impact their health, safety, fundamental rights, socio-economic well-being or any other of their rights deriving from the obligations laid down in this Regulation, shall receive from the provider or the user, at the time when the decision is communicated, a

clear and meaningful explanation pursuant to Article 13(1) on the role of the AI system in the decision-making procedure, the main parameters of the decision taken and on the related input data.

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

(a) for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law, which lays down other appropriate safeguards for the affected persons' rights, freedoms and legitimate interests; or

(b) where the affected person has given free, explicit, specific and informed consent not to receive an explanation. The affected person shall have the right to withdraw his or her consent not to receive an explanation at any time. Prior to giving consent, the affected person shall be informed thereof. It shall be as easy to withdraw as to give consent.

Amendment 151

Proposal for a regulation Article 69 d (new)

Text proposed by the Commission

Amendment

Article 69d

Representative actions

1. The following is added to Annex I of Directive (EU) 2020/1828 on Representative actions for the protection of the collective interests of consumers:

“Regulation xxxx/xxxx of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts”.

Amendment 152

Proposal for a regulation TITLE X – title

Text proposed by the Commission

CONFIDENTIALITY AND PENALTIES

Amendment

CONFIDENTIALITY, **REMEDIES** AND
PENALTIES

Amendment 153

Proposal for a regulation Article 84 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Within [three years after the date of application of this Regulation referred to in Article 85(2)], the Commission shall evaluate the effectiveness of the Board to carry out its tasks and assess whether an EU Agency would be best placed to ensure an effective and harmonised implementation of this Regulation.

Amendment 154

Proposal for a regulation Annex VIII – point 5 a (new)

Text proposed by the Commission

Amendment

5a. The outcome of the trustworthy technology assessment;

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts		
References	COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)		
Committees responsible Date announced in plenary	IMCO 7.6.2021	LIBE 7.6.2021	
Opinion by Date announced in plenary	JURI 7.6.2021		
Associated committees - date announced in plenary	16.12.2021		
Rapporteur for the opinion Date appointed	Axel Voss 10.1.2022		
Rule 58 – Joint committee procedure Date announced in plenary	16.12.2021		
Discussed in committee	26.1.2022	15.3.2022	28.3.2022
Date adopted	5.9.2022		
Result of final vote	+: –: 0:	17 1 0	

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

17	+
ID	Jean-François Jalkh
NI	Sabrina Pignedoli
PPE	Pascal Arimont, Angelika Niebler, Luisa Regimenti, Axel Voss, Elissavet Vozemberg-Vrionidi, Marion Walsmann, Javier Zarzalejos
RENEW	Ilana Cicurel, Pascal Durand, Karen Melchior, Adrián Vázquez Lázara
S&D	René Repasi, Tiemo Wölken, Lara Wolters
VERTS/ALE	Heidi Hautala

1	-
THE LEFT	Cornelia Ernst

0	0

Key to symbols:

+ : in favour

- : against

0 : abstention