



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

01/06/2022

AMENDMENTS: 185

Brando Benifei, Dragoş Tudorache

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

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

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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01/06/2022

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

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

Amendment 1

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Miţuţa

Proposal for a regulation

Recital 8

Text proposed by the Commission

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the

Amendment

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the

case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems in question by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

The notion of remote biometric identification system shall not include authentication and verification systems whose purpose is to confirm, based on prior consent, that a specific natural person is the person he or she claims to be or to confirm the identity of a natural person for the purpose of having access to a service, a device or premises.

Or. en

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Amendment 2

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Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI

Amendment

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI

system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations.

system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and users of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations. ***This exception should nevertheless be limited to trusted countries and international organizations that share the Union's values.***

Or. en

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Amendment 3

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituța**

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

Amendment

(16) The placing on the market, putting into service or use of certain AI systems intended to distort human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. ***In particular, AI systems that*** deploy subliminal components ***that natural persons*** cannot perceive, ***that*** exploit ***the*** vulnerabilities of ***any groups, or that use purposefully manipulative techniques*** 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 ***or to their rights or to the values of the Union should be prohibited.*** The intention may not be presumed if the distortion of human behaviour results from factors external to the AI system which are

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.

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 *inhuman-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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Amendment 4

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Recital 17

Text proposed by the Commission

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

Amendment

(17) AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics ***using trustworthiness, good citizenship, patriotism, deviancy, or any other such metric as a proxy***. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are

collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. ***This detrimental treatment can also be effected by providing undue and unjustified privileges to groups of people based on their social score.*** Such AI systems should be therefore prohibited.

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Amendment 5

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Recital 18

Text proposed by the Commission

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

Amendment

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

by law enforcement activities.

should therefore be prohibited.

Or. en

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Amendment 6

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Dragoș Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation

Recital 19

Text proposed by the Commission

Amendment

(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA³⁸ if those criminal offences are punishable in the Member State concerned by a

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custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.

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

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Dragoş Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Recital 20

Text proposed by the Commission

Amendment

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

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threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.

Or. en

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Dragoș Pîslaru, Irena Joveva, Sophia in 't Veld, Karen Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

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

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in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.

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Amendment 9

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Sophia in 't Veld, Karen
Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation

Recital 22

Text proposed by the Commission

Amendment

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

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Or. en

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Amendment 10

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Dragoş Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Recital 23

Text proposed by the Commission

Amendment

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

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

Or. en

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Amendment 11

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Dragoș Pîslaru, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation

Recital 24

Text proposed by the Commission

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

Amendment

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

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Amendment 12

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Proposal for a regulation

Recital 27

Text proposed by the Commission

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

Amendment

(27) High-risk AI systems should only be placed on the Union market or put into service if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union **or to Union values as enshrined in Article 2 TEU** and such limitation minimises any potential restriction to international trade,

if any.

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Amendment 13

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Proposal for a regulation

Recital 32

Text proposed by the Commission

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

Amendment

(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves products, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a high risk of harm to the health, safety or the fundamental rights of persons *or to Union values as enshrined in Article 2 TEU*, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in the Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI

systems. *Such systems should be classified as high-risk only insofar as they are built and operated with biometric, biometrics-based, or personal data or they influence decisions of natural persons or make decisions or influence decisions affecting natural persons. This ensures that, when referencing AI systems in pre-defined areas of human activity, this Regulation does not inadvertently apply to AI systems that can have no impact on the health, safety, fundamental rights of natural persons or the values of the Union as enshrined in Article 2 TEU.*

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Amendment 14

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Proposal for a regulation

Recital 34

Text proposed by the Commission

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

Amendment

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

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Amendment 15

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Recital 36

Text proposed by the Commission

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in

Amendment

(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for **personalized** task allocation **based on personal, biometric, or biometric data**, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this

the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

Or. en

EUROPEAN PARLIAMENT

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

01/06/2022

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

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

Amendment 16

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituţa

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an

Amendment

(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an

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

effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, explainable and documented. It is therefore appropriate to classify as high-risk a number of AI systems intended to be used in the law enforcement context where accuracy, reliability and transparency is particularly important to avoid adverse impacts, retain public trust and ensure accountability and effective redress. In view of the nature of the activities in question and the risks relating thereto, those high-risk AI systems should include in particular AI systems intended to be used by law enforcement authorities for individual risk assessments, polygraphs and similar tools or to detect the emotional state of natural person, to detect ‘deep fakes’, for the evaluation of the reliability of evidence in criminal proceedings, for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 17

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Proposal for a regulation

Recital 40 a (new)

Text proposed by the Commission

Amendment

(40 a) When the “deep fake” content forms part of an evidently artistic, creative, or fictional cinematographic and analogous work, or when the “AI authors” generate content that undergoes human review and for the publication of which a natural or legal person established in the Union is liable or holds editorial responsibility, the AI systems should not be considered high-risk but should nevertheless be subject to adequate transparency requirements, where appropriate.

Or. en

EUROPEAN PARLIAMENT

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Amendment 18

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation
Recital 40 b (new)

Text proposed by the Commission

Amendment

(40 b) Subliminal techniques are techniques that expose natural persons to sensorial stimuli that the natural persons cannot consciously perceive but that are assumed to register in the brain unconsciously, such as flashing images or text for fractions of a second or playing sounds outside the range of perceptible hearing. AI systems deploying such techniques should be prohibited, because these techniques are by their very nature intended to be manipulative. Nevertheless, exceptions are warranted for AI systems using subliminal techniques for research and therapeutical purposes, based on the consent of the natural persons that are being exposed to them. In such limited cases, the AI systems should be considered high-risk and comply with the

*requirements for high-risk AI systems as
set forth in this Regulation.*

Or. en

EUROPEAN PARLIAMENT

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Justice and Home Affairs

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Amendment 19

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Svenja Hahn, Andrus Ansip,
Dita Charanzová, Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.

Amendment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider. ***These requirements should be objective-driven, fit to purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators.***

Or. en

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Amendment 20

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Róza Thun und Hohenstein, Alin Mituţa

Proposal for a regulation

Recital 58

Text proposed by the Commission

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

Amendment

(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard the need to ensure proper monitoring of the performance of an AI system in a real-life setting, it is appropriate to set specific responsibilities for users. Users should in particular use high-risk AI systems in accordance with the instructions of use and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate. ***Given the potential impact and the need for democratic oversight and scrutiny, users of high-risk AI systems that are public***

authorities or Union institutions, bodies, offices and agencies should be required to conduct a fundamental rights impact assessment prior to commencing the use of a high-risk AI system and to register the use of any high-risk AI systems in a public database.

Or. en

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Amendment 21

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Alin Mituța**

Proposal for a regulation

Recital 65

Text proposed by the Commission

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

Amendment

(65) In order to carry out third-party conformity *assessments when so required*, notified bodies should be designated under this Regulation by the national competent authorities, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.

Or. en

EUROPEAN PARLIAMENT

Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 22

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen
Melchior, Alin Mituța**

Proposal for a regulation

Recital 68

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 23

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Andrus Ansip,
Dita Charanzová, Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Recital 71

Text proposed by the Commission

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

Amendment

(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, Member States should establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. ***Member States should ensure that the regulatory sandboxes have the adequate***

into service.

*financial and human resources for their
proper functioning.*

Or. en

EUROPEAN PARLIAMENT

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Amendment 24

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen Melchior, Alin Mituţa**

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 *ensure an* effective and harmonised implementation of this Regulation, *to achieve a high level of trustworthiness and of protection of health, safety, fundamental rights and the Union values enshrined in Article 2 TEU across the Union with regards to artificial intelligence systems, to actively support Member States, Union institutions, bodies, offices and agencies in matters pertaining to this Regulation, to reduce the fragmentation of the internal market, and to increase the uptake of artificial intelligence throughout the Union, an European Union Artificial Intelligence Office* should be established. The *AI Office should have legal personality, should act in full independence, and should be adequately funded and staffed.*

Member States should provide the strategic direction and control of the AI Office through the management board of the AI Office, alongside the Commission, the EDPS, and the FRA. An executive director should be responsible for the coordination of the AI Office's operations and for the implementation of its work programme. Industry, start-ups and SMEs, and civil society should formally participate in the work of the AI Office through an advisory forum that should ensure varied stakeholder representation and should advise the AI Office on matters pertaining to this Regulation.

Or. en

EUROPEAN PARLIAMENT

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

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Amendment 25

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituţa**

Proposal for a regulation

Recital 81

Text proposed by the Commission

(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The

Amendment

(81) The development of AI systems other than high-risk AI systems in accordance with the requirements of this Regulation may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct intended to foster the voluntary application of the mandatory requirements applicable to high-risk AI systems ***or risk-appropriate codes of conduct that sufficiently increase trust in the underlying technology that is not high-risk***. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability,

Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.

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

Or. en

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Amendment 26

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituța

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

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. 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.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

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 *with industry, civil society, other stakeholders, and* 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. 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.

⁵⁸ OJ L 123, 12.5.2016, p. 1.

Or. en

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Amendment 27

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

***(e a) rules for the establishment and
functioning of the European Union
Artificial Intelligence Office;***

Or. en

EUROPEAN PARLIAMENT

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Amendment 28

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituţa, Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

***(e b) measures in support of innovation,
including the setting up of regulatory
sandboxes, and measures to reduce the
regulatory burden on SMEs and start-ups.***

Or. en

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Amendment 29

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Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission

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

Amendment

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States ***and are subject of a decision of the Commission adopted in accordance with Article 36 of Directive (EU)2016/680 or Article 45 of Regulation 2016/679 ('adequacy decision') or are part of an international agreement concluded between the Union and that third country or international organisation pursuant to Article 218 TFEU adducing adequate safeguards***

*with respect to the protection of privacy
and fundamental rights and freedoms of
individuals;*

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 30

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Proposal for a regulation

Article 2 a (new)

Text proposed by the Commission

Amendment

Article 2 a

Metaverse environments

1. This regulation shall apply, mutatis mutandis, to operators of AI systems operating in virtual environments that can be accessed by natural persons in the Union that fulfil all the following criteria ('metaverse environments'):

- (i) they require natural persons to have a uniquely identifiable and permanent representation within the virtual environment that is legally and economically connected to them via an official identity document, a digital identity, a digital wallet, or equivalent;*
- (ii) they are built for social and economic interaction on a large scale;*

(iii) they allow natural persons to behave and interact virtually in manners that are consistent with their real-world behaviours and interactions and that can be analysed to infer real-world characteristics, including personal data;

(iv) they allow natural persons to engage in real-world financial transactions, including through blockchain-backed digital currencies and non-fungible tokens;

(v) they allow for such interactions between natural persons as to make possible risks to the health, safety, or fundamental rights of natural persons or to bring prejudice to the values of the Union as enshrined in Article 2 TEU.

Or. en

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Amendment 31

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

Article 3 – paragraph 1 – point 33 a (new)

Text proposed by the Commission

Amendment

*(33 a) ‘subliminal techniques’ means
techniques that use sensorial stimuli such
as images, text, or sounds, that are below
the limits of conscious human sensorial
perception;*

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 32

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani,
Alin Mituţa**

Proposal for a regulation

Article 3 – paragraph 1 – point 35 a (new)

Text proposed by the Commission

Amendment

***(35 a) ‘remote biometric categorisation
system’ means a biometric categorisation
system capable of categorising natural
persons at a distance;***

Or. en

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

Amendment 33

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța, Michal Šimečka**

Proposal for a regulation

Article 3 – paragraph 1 – point 36

Text proposed by the Commission

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

Amendment

(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified, , ***excluding authentication and verification systems whose sole purpose is to confirm, based on prior consent, that a specific natural person is the person he or she claims to be or to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises;***

Or. en

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Amendment 34

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation

Article 3 – paragraph 1 – point 42

Text proposed by the Commission

(42) ‘national supervisory authority’ means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State *at the European Artificial Intelligence* Board;

Amendment

(42) ‘national supervisory authority’ means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State *in the management* board of *the AI Office*;

Or. en

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Amendment 35

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques, *with the exception of AI systems using such techniques for scientific research and for approved therapeutic purposes on the basis of explicit consent of the natural persons that are exposed to them, which systems shall be classified as high risk for the purposes of this Regulation*;

Or. en

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Amendment 36

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Proposal for a regulation

Article 5 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) The placing on the market, putting into service or use of an AI system that deploys purposefully manipulative or deceptive techniques in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm, infringe on that person's or another person's fundamental rights, or contravene the Union values enshrined in Article 2 TEU;

Or. en

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Amendment 37

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Dragoș Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani,
Karen Melchior, Alin Mituța, Michal Šimečka**

Proposal for a regulation

Article 5 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 38

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 1 – point c – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 39

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Andrus Ansip, Dita Charanzová, Morten Løkkegaard, Alin Mituţa

Proposal for a regulation

Article 5 – paragraph 1 – point c – point i

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 40

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission

Amendment

*(ii a) privileged treatment of certain
natural persons or whole groups thereof
in social contexts that are unrelated to the
contexts in which the data was originally
generated or collected;*

Or. en

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Amendment 41

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Dragoş Pîslaru, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Róza Thun
und Hohenstein, Alin Mituţa**

Proposal for a regulation

Article 5 – paragraph 1 – point d – introductory part

Text proposed by the Commission

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

Amendment

(d) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces

Or. en

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Amendment 42

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Dragoș Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen
Melchior, Svenja Hahn, Róza Thun und Hohenstein, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 1 – point d – point i

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 43

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Dragoș Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen
Melchior, Svenja Hahn, Róza Thun und Hohenstein, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 44

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Proposal for a regulation

Article 5 – paragraph 1 – point d – point iii

Text proposed by the Commission

Amendment

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

deleted

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

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Amendment 45

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituţa**

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. The use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:

deleted

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

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

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

Or. en

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Amendment 46

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Dragoș Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen
Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 2 – point a

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 47

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Dragoş Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen
Melchior, Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Article 5 – paragraph 2 – point b

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 48

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Dragoș Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation

Article 5 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 49

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Dragoș Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation
Article 5 – paragraph 3

Text proposed by the Commission

Amendment

3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use.

deleted

The competent judicial or administrative

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

Or. en

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Amendment 50

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Dragoş Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 51

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Dragoș Pîslaru, Sophia in 't Veld, Irena Joveva, Karen Melchior, Svenja Hahn, Alin Mituța**

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission

Amendment

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

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purpose of law enforcement.

Or. en

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Amendment 52

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

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

Amendment

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk, ***with the exception of those AI systems that are not safety components of a product and that fulfil both of the following conditions:***

(a) they are not developed with and do not use biometric data, biometrics-based data, or personal data as inputs;

(b) they are not intended to influence decisions of natural persons or to make decisions or to assist in the making of decisions affecting natural persons.

Or. en

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Amendment 53

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Morten Løkkegaard, Alin Mituța, Michal Šimečka**

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall comply with the requirements established in this Chapter.

Amendment

1. ***1. Operators of*** high-risk AI systems shall comply with the requirements established in this Chapter.

Or. en

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Amendment 54

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 8 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. In complying with the requirements established in this Chapter, operators of high-risk AI systems shall take into account the generally-acknowledged state of the art, including as reflected in the relevant harmonised standards and common specifications referenced in Articles 40 and 41.

Or. en

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Amendment 55

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Amendment

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems. . ***The risk management system can be integrated into, or a part of, already existing risk management procedures insofar as it fulfils the requirements of this article.***

Or. en

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Amendment 56

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

(a) identification and analysis of the known and ***reasonably*** foreseeable risks associated with each high-risk AI system ***with respect to health, safety, fundamental rights, and the values of the Union as enshrined in Article 2 TEU;***

Or. en

EUROPEAN PARLIAMENT

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

01/06/2022

Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain
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Proposal for a regulation COM(2021)0206 - C9-0146/2021 – 2021/0106(COD)

Amendment 57

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Andrus Ansip,
Dita Charanzová, Alin Mituţa**

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 58

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – 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 **(a) and** (b) of this Article, and, where appropriate, training to users.

Or. en

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Amendment 59

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Āuriř Nicholsonov, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Lkkegaard, Alin Mituţa, Michal řimečka

Proposal for a regulation Article 9 – paragraph 8

Text proposed by the Commission

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children *or natural persons suffering from disabilities that render them legally unable to give their consent.*

Or. en

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Amendment 60

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Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of **relevant** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

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Amendment 61

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or equivalent documentation meeting the same objectives, subject to the approval of the competent authority.*

Or. en

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Amendment 62

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in *Annex IV* as well as the information required under those legal acts.

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in *paragraph 1* as well as the information required under those legal acts.

Or. en

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Amendment 63

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation

Article 23 – title

Text proposed by the Commission

Cooperation with competent authorities

Amendment

Cooperation with competent authorities,
the AI Office and the Commission

Or. en

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Amendment 64

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

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

Amendment

Providers of high-risk AI systems ***and where applicable, users*** shall, upon request by a national competent authority ***or where applicable, by the AI Office or the Commission***, provide ***them*** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned.

Or. en

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Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain
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Proposal for a regulation COM(2021)0206 - C9-0146/2021 – 2021/0106(COD)

Amendment 65

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Alin Mituța, Michal Šimečka**

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Upon a reasoned request by a national competent authority or, where applicable, by the Commission, providers and, where applicable, users shall also give the requesting national competent authority or the Commission, as applicable, access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise bylaw. The national competent authorities or, where applicable, the Commission, shall keep confidential all trade secrets contained in the information received, in accordance with Article 70(2).

Or. en

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Amendment 66

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituţa, Michal Šimečka

Proposal for a regulation

Article 27 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 67

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation
Article 27 – paragraph 5

Text proposed by the Commission

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

Amendment

5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation *in its possession or available to it, in accordance with the obligations of distributors as outlined by this Regulation, that are* necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority.

Or. en

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Amendment 68

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 28 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Providers that initially placed the high-risk AI system on the market or put it into service shall cooperate closely with distributors, importers, users, or other third-parties to supply them with the necessary information or documentation in their possession that is required for the fulfilment of the obligations set out in this Regulation, in particular at the moment when such distributors, importers, users or other third-parties become the new providers as determined in paragraph 1 and the initial providers are no longer considered a provider for the purposes of this Regulation as determined in paragraph 2.

Or. en

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Amendment 69

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Alin Mituţa, Michal Šimečka

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 use such systems **and implement human oversight** in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5.

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 70

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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 in view of the intended purpose of the high-risk AI system. ***To the extent the user exercises control over the high-risk AI system, that user shall also ensure that relevant and appropriate robustness and cybersecurity measures are in place and are regularly adjusted or updated.***

Or. en

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Amendment 71

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Róza Thun und
Hohenstein, Alin Mituța**

Proposal for a regulation

Article 29 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

***5 a. Users of high-risk AI systems that
are public authorities or Union
institutions, bodies, offices and agencies
shall conduct a fundamental rights impact
assessment prior to commencing the use
of a high-risk AI system;***

Or. en

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Amendment 72

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin
Mituţa**

Proposal for a regulation

Article 40 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

***The Commission shall issue
standardisation requests covering all
essential requirements of this Regulation
in accordance with Article 10 of
Regulation 1025/2012 no later than 6
months after the date of entry into force
of this Regulation.***

Or. en

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Amendment 73

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin
Mituţa**

Proposal for a regulation

Article 41 – paragraph 1

Text proposed by the Commission

1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Amendment

1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission ***shall issue a standardisation request to one or several of the European standardization organizations in accordance with Article 10 of Regulation 1025/2012 and*** may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title, ***which shall only be valid until the requested harmonised standards have been elaborated and published in the Official Journal of the European Union.***

Those implementing acts shall be adopted
in accordance with the examination
procedure referred to in Article 74(2).

Or. en

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Amendment 74

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Proposal for a regulation

Article 41 – paragraph 2

Text proposed by the Commission

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law.

Amendment

2. The Commission, when preparing the common specifications referred to in paragraph 1, shall gather the views of relevant ***stakeholders, including industry, start-ups, and SMEs, and of relevant*** bodies or expert groups established under relevant sectorial Union law.

Or. en

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Amendment 75
Dragoş Tudorache

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 natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use.

Or. en

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Amendment 76
Dragoş Tudorache

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 shall inform of the operation of the system the natural persons exposed thereto.

Or. en

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Amendment 77
Dragoş Tudorache

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

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

However, the first subparagraph shall not apply where it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.

Or. en

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Amendment 78

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Morten
Løkkegaard, Alin Mituța**

Proposal for a regulation
Article 53 – paragraph 1

Text proposed by the Commission

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

Amendment

1. *Member States shall establish AI regulatory sandboxes, which shall be operational by [24 months following the entering into force of this Regulation], and shall ensure that the competent authorities responsible for the regulatory sandboxes have sufficient resources available to fulfil their duties effectively and in a timely manner. Regulatory sandboxes can also be established at local, regional or European level.*

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Amendment 79

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituţa

Proposal for a regulation

Article 53 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

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

sandbox.

Or. en

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Amendment 80

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Morten Løkkegaard, Alin Mituța**

Proposal for a regulation
Article 53 – paragraph 5

Text proposed by the Commission

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

Amendment

5. **National** competent authorities shall coordinate their activities and cooperate within the framework of the **AI Office**. They shall submit annual reports to the **AI Office** and the Commission on the results **of** the implementation of those scheme, including good practices, **incidents**, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation **another** Union legislation supervised within the sandbox. **Those reports or abstracts thereof shall be made available to the public in order to further enable innovation in the Union.**

Or. en

EUROPEAN PARLIAMENT

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

01/06/2022

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

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

Amendment 81

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Morten Løkkegaard, Alin Mituţa

Proposal for a regulation

Article 53 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Regulatory sandboxes shall allow and facilitate the testing of possible adaptations of the regulatory framework governing artificial intelligence in order to enhance innovation or reduce compliance costs, without prejudice to the provisions of this Regulation or to the health, safety, fundamental rights of natural persons or to the values of the Union as enshrined in Article 2 TEU. The results and lessons learned from such tests shall be submitted to the AI Office and the Commission.

Or. en

EUROPEAN PARLIAMENT

Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Proposal for a regulation COM(2021)0206 - C9-0146/2021 – 2021/0106(COD)

Amendment 82

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 53 – paragraph 6

Text proposed by the Commission

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Amendment

6. The modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2) ***no later than 12 months following the entry into force of this Regulation and shall ensure, inter alia:***

(a) that they allow start-ups to use their participation in the sandbox in order to fulfil, in a guided environment with significantly reduced costs, the conformity

assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69;

(b) that adequate resources are dedicated to the establishment and functioning of the regulatory sandboxes so that the regulatory sandboxes can ensure broad access and keep up with demand for participation without creating disincentivising backlogs or delays;

(c) that procedures, processes, and bureaucratic requirements for application, selection, participation, and exiting the sandbox are simple, easily intelligible, clearly communicated, and streamlined so as to facilitate the participation of startups with limited legal and bureaucratic capacities;

(d) that procedures, processes, and bureaucratic requirements for application, selection, participation, and exiting the sandbox are streamlined across the Union and that participation in a regulatory sandbox established by a Member State by virtue of its obligation in paragraph 1 or by the Commission is uniformly recognised and carries the same legal effects across the Union.

Or. en

EUROPEAN PARLIAMENT

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Amendment 83

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța, Michal Šimečka**

Proposal for a regulation

Article 53 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

**6 a. The Commission shall draw up
guidelines for the proper establishment,
development, implementation,
functioning, and supervision of regulatory
sandboxes.**

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 84

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Proposal for a regulation

Article 54 – paragraph 1 – introductory part

Text proposed by the Commission

1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of developing and testing certain innovative AI systems in the sandbox ***under*** the following conditions:

Amendment

1. In the AI regulatory sandbox personal data lawfully collected for other purposes shall be processed for the purposes of developing and testing certain innovative AI systems in the sandbox ***when all of*** the following conditions ***are met***:

Or. en

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Amendment 85

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituța

Proposal for a regulation

Article 54 – paragraph 1 – point a – point i

Text proposed by the Commission

(i) the ***prevention***, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against ***and the prevention of*** threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;

Amendment

(i) the investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;

Or. en

EUROPEAN PARLIAMENT

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Amendment 86

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Alin Mituţa

Proposal for a regulation

Article 54 – paragraph 1 – point j

Text proposed by the Commission

(j) a short summary of the AI project developed in the sandbox, its objectives and expected results published on the website of the competent authorities.

Amendment

(j) a short summary of the AI project developed in the sandbox, its objectives, ***hypotheses*** and expected results, ***and non-confidential testing results, is*** published on the website of the competent authorities.

Or. en

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Amendment 87

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation

Title VI – Chapter 1 – title

Text proposed by the Commission

Amendment

1 European Artificial Intelligence
Board

European Artificial Intelligence **Office**

Or. en

Justification

This change shall be consistently reflected throughout the entire Regulation

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Amendment 88

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation

Article 56 – title

Text proposed by the Commission

Amendment

Establishment of the European Artificial
Intelligence **Board**

Establishment of the European Artificial
Intelligence **Office**

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 89

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission

Amendment

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

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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01/06/2022

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

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Amendment 90

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation
Article 56 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

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

(b) coordinate and contribute to guidance and analysis by the Commission and the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation;

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

Regulation.

Or. en

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Amendment 91

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa

Proposal for a regulation
Article 56 a (new)

Text proposed by the Commission

Amendment

Article 56 a

SECTION 1: General provisions

An independent ‘European Artificial Intelligence Office’ (the ‘AI Office’) is hereby established. The European Union Artificial Intelligence Office shall be an Office of the Union, shall have legal personality, and shall be adequately funded and staffed. The Office shall enjoy in all the Member States the most extensive legal capacity accorded to legal persons under their laws.

Or. en

EUROPEAN PARLIAMENT

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Amendment 92

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa

Proposal for a regulation

Article 56 b (new)

Text proposed by the Commission

Amendment

Article 56 b

Mandate

1. The AI Office shall carry out the tasks assigned to it under this Regulation for the purpose of achieving a high level of trustworthiness and of protection of health, safety, fundamental rights and the Union values enshrined in Article 2 TEU across the Union with regards to artificial intelligence systems, including by actively supporting Member States, Union institutions, bodies, offices and agencies in matters pertaining to this Regulation. The AI Office shall act as a reference point for advice and expertise on artificial intelligence for Union institutions, bodies, offices and agencies, for Member States and their national supervisory authorities,

as well as for other relevant Union stakeholders.

2. The AI Office shall contribute to reducing the fragmentation of the internal market and to increasing the uptake of artificial intelligence throughout the Union by carrying out the tasks assigned to it under this Regulation.

3. When carrying out its tasks, the AI Office shall act independently while avoiding the duplication of Member State activities and taking into consideration Member State competences.

4. The AI Office shall organise consultations with stakeholders twice a year to assess the evolution of trends in technology, issues related to the implementation and the effectiveness of this Regulation, regulatory gaps or loopholes observed in practice. Such stakeholders shall include representatives from industry, start-ups and SMEs, civil society organisations, such as NGOs, consumer associations, the social partners and academia.

5. The AI Office may consult national authorities, such as national equality bodies, where the issues discussed are of relevance for them. The AI Office may also consult, where appropriate, external experts and observers and interested third parties, including stakeholders such as those referred to in paragraph 5, and may hold exchanges with them.

6. The AI Office shall cooperate with Union institutions, bodies, offices, agencies and advisory groups and shall make the results of that cooperation publicly available.

Or. en

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Amendment 93

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen Melchior, Alin Mituţa

Proposal for a regulation
Article 56 c (new)

Text proposed by the Commission

Amendment

Article 56 c

*Accountability, transparency, and
independence*

- 1. The AI Office shall be accountable to the European Parliament and to the Council in accordance with this Regulation.*
- 2. The AI Office shall develop good administrative practices in order to ensure the highest possible level of transparency concerning its activities. Regulation (EC) No 1049/2001 shall apply to documents held by the AI Office.*
- 3. The AI Office shall fulfil its tasks in complete independence.*

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

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Amendment 94

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation
Article 56 d (new)

Text proposed by the Commission

Amendment

Article 56 d

Administrative and management structure

1. The administrative and management structure of the AI Office shall comprise:

(a) a management board

(b) an executive director

(c) an advisory forum

(d) where appropriate, other advisory bodies established by the management board to support the AI Office in technical or scientific matters related to this Regulation.

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 95

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa

Proposal for a regulation
Article 56 e (new)

Text proposed by the Commission

Amendment

Article 56 e

Objectives

1. The AI Office shall:

(a) contribute to the uptake of artificial intelligence in the Union, including through supporting innovation and the development of regulatory sandboxes provided for in this Regulation;

(b) contribute to a high level of trustworthiness and of protection of health, safety, fundamental rights and the Union values enshrined in Article 2 TEU with regard to artificial intelligence systems in the Union;

(c) contribute to the effective cooperation of the national supervisory authorities and the Commission with regard to

matters covered by this Regulation;

(d) provide forecasts, guidance, and analysis to the Commission, Member States, and to the national supervisory authorities and other competent authorities on emerging issues across the internal market with regard to matters covered by this Regulation and related issues;

(e) contribute to the effective and consistent application of this Regulation and assist Member States, the national supervisory authorities, and the Commission in this regard;

(f) contribute to the effective cooperation with the competent authorities of third countries and with international organisations;

(g) contribute to the development, promotion, and adoption of harmonized standards, common specifications, common benchmarking standards, and voluntary codes of conduct;

(h) contribute to the effective and consistent enforcement of this Regulation throughout the Union, including by issuing binding decisions with regard to cases involving two or more Member States asset out in Article 59b.

Or. en

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Amendment 96

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation
Article 57

Text proposed by the Commission

Amendment

Article 57

deleted

Structure of the Board

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.

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.

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.*

4. *The Board may invite external experts and observers to attend its meetings and may hold exchanges with interested third parties to inform its activities to an appropriate extent. To that end the Commission may facilitate exchanges between the Board and other Union bodies, offices, agencies and advisory groups.*

Or. en

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Amendment 97

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Proposal for a regulation
Article 57 a (new)

Text proposed by the Commission

Amendment

Article 57 a

Composition of the management board

- 1. The management board shall be composed of one representative of each Member State, the Commission, and the European Data Protection Supervisor, and the Fundamental Rights Agency. Each Member State and the Commission shall have one vote. The EDPS and the FRA shall not have voting rights.***
- 2. Each member of the management board shall have an alternate. That alternate shall represent the member in the member's absence.***
- 3. The Commission and the Member States shall aim to achieve gender balance on the management board.***

4. The list of the members and alternate members of the management board shall be made public and shall be updated by the AI Office on its web site.

5. The term of office of the members of the management board and their alternates shall be four years. That term shall be renewable once.

Or. en

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Amendment 98

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Proposal for a regulation
Article 57 b (new)

Text proposed by the Commission

Amendment

Article 57 b

Functions of the management board

1. The management board shall be responsible for taking the strategic decisions of the AI Office in accordance with this Regulation. In particular, the management board shall:

(a) Establish the general direction of the operation of the AI Office and ensure that the AI Office operates in accordance with the rules and principles laid down in this Regulation;

(b) Adopt, on the basis of the draft submitted by the Office's executive director and after the Commission has delivered an opinion, the single programming document of the AI Office

containing, inter alia, the AI Office's multiannual programming and its work programme for the following year. The single programming document shall be transmitted to the European Parliament, the Council and the Commission;

(c) Appoint the executive director and, where relevant, extend his or her term of office or remove him or her from office;

(d) Produce, on the basis of a draft drawn up by the executive director, the estimate budget of the AI Office for the following financial year. This estimate, which shall initially include a draft establishment plan by the date of entry into force of this Regulation, shall be transmitted by the management board to the Commission within the first quarter of each year;

(e) Adopt the AI Office's annual draft and final budgets;

(f) Assess and adopt the consolidated annual report on the AI Office activities, including an evaluation based on performance indicators; submit both the annual report and the assessment thereof to the European Parliament, to the Council, to the Commission and to the Court of Auditors, and make the annual report public;

(g) Adopt the AI Office's rules of procedure on the basis of the draft submitted by the executive director after the Commission has delivered an opinion;

(h) Take decisions, based on the executive director's recommendation, concerning the establishment of the AI Office's internal structures and, where necessary, the modification of those internal structures, taking into consideration technological developments that may create additional operational needs and having regard to sound budgetary management;

Or. en

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Amendment 99

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Proposal for a regulation
Article 57 c (new)

Text proposed by the Commission

Amendment

Article 57 c

Meetings of the management board

- 1. The meetings of the management board shall be convened by the Chair. The Chair shall prepare the agenda of the meetings in accordance with the tasks of the Board pursuant to this Regulation and with its rules of procedure.*
- 2. The meetings of the management board shall be considered to be quorate where at least two-thirds of its members are present.*
- 3. The management board shall hold at least two ordinary meetings a year. It shall also hold extraordinary meetings at the request of the Chair, at the request of the Commission, or at the request of at*

least one third of its members.

4. The executive director shall take part in the meetings of the management board but shall not have the right to vote.

5. Members of the advisory forum may take part in the meetings of the management board at the invitation of the Chair, but shall not have the right to vote.

6. The members of the management board and their alternates may be assisted at the meetings of the management board by advisers or experts, subject to the rules of procedure of the management board.

7. The AI Office shall provide the secretariat of the management board and support the management Board in its operations.

Or. en

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Amendment 100

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation
Article 57 c (new)

Text proposed by the Commission

Amendment

Article 57 c

Chair of the management board

1. The management board shall elect a Chair and a deputy Chair from among its voting members by simple majority. The term of office of the Chair and of the deputy Chair shall be three years. The terms of the Chair and of the deputy Chair may be renewed once. The Deputy Chair shall replace the Chair ex officio if the Chair is unable to attend to his or her duties.

Or. en

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Amendment 101

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa

Proposal for a regulation
Article 57 d (new)

Text proposed by the Commission

Amendment

Article 57 d

Voting rules of the management board

- 1. The management board shall take its decisions by a majority of its members, unless otherwise provided for in this Regulation.*
- 2. A majority of two-thirds of the members of the management board shall be required for the adoption of the single programming document and of the annual budget and for the appointment, extension of the term of office or removal of the executive director.*
- 3. Each member shall have one vote. In the absence of a member, their alternate shall be entitled to exercise the member's right to vote.*

4. The Chair of the management board shall take part in the voting.

5. The executive director shall not take part in the voting.

6. The management board's rules of procedure shall establish more detailed voting arrangements, in particular the circumstances in which a member may act on behalf of another member.

Or. en

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Justice and Home Affairs*

01/06/2022

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

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

Amendment 102

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation
Article 58 – title

Text proposed by the Commission

Amendment

Tasks *of the Board*

Tasks

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Union Legislative Acts

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Amendment 103

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

Proposal for a regulation

Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

*In fulfilling its objectives, the AI Office
shall in particular:*

Or. en

EUROPEAN PARLIAMENT

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Amendment 104

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(a a) issue opinions, recommendations
or written contributions on matters related
to the implementation of this Regulation;*

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 105

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa, Michal Šimečka

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(a b) examine, on its own initiative or on request of its management board, any question covering the application of this Regulation and issue guidelines, recommendations and best practices with a view to ensuring the consistent implementation of this Regulation;

Or. en

EUROPEAN PARLIAMENT

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

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Amendment 106

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(a c) provide the Commission, in the cases referred to in Article 68a (1)(a) and(1)(b), with all the available information at its disposal, including market studies, impact assessments, and analyses referred to in paragraph (f) of this article, to prepare the decision for triggering the Commission's intervention and opening of proceedings pursuant to Article 68a;

Or. en

EUROPEAN PARLIAMENT

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Amendment 107

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(a d) assist Member States in developing
the organizational and technical expertise
required for the implementation of this
Regulation;*

Or. en

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Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Proposal for a regulation COM(2021)0206 - C9-0146/2021 – 2021/0106(COD)

Amendment 108

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 58 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) contribute to uniform practices in
the Member States, including ***by assisting
Member States, the Commission, and,
where applicable, other authorities in the
establishment, development, and
functioning of regulatory sandboxes
referred to in Article 53, including by
providing input and support in drafting
the delegated acts referred to in Article
53(6);***

Or. en

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Amendment 109

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

***(b a) Support innovation by
coordinating the exchange of information
and good practices and by facilitating the
cooperation among regulatory sandboxes
established according to Article 53 and by
making available on its website the
information referred to in Article 53 (5).***

Or. en

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Amendment 110

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 58 – paragraph 1 – point c – introductory part

Text proposed by the Commission

(c) issue opinions, recommendations *or*
written contributions on matters related to
the *implementation of this Regulation, in
particular*

Amendment

(c) issue opinions, recommendations,
written contributions, *or studies* on matters
related to the *technical specifications or
existing standards regarding the
requirements set out in Title III, Chapter
2 and on the use of harmonised standards
or common specifications referred to in
Articles 40 and 41;*

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain
Union Legislative Acts

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

Amendment 111

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 58 – paragraph 1 – point c – point i

Text proposed by the Commission

Amendment

*(i) on technical specifications or
existing standards regarding the
requirements set out in Title III, Chapter
2,*

deleted

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Union Legislative Acts

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Amendment 112

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 58 – paragraph 1 – point c – point ii

Text proposed by the Commission

Amendment

**(ii) on the use of harmonised
standards or common specifications
referred to in Articles 40 and 41,**

deleted

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Union Legislative Acts

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

Amendment 113

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 58 – paragraph 1 – point c – point iii

Text proposed by the Commission

Amendment

*(iii) on the preparation of guidance
documents, including the guidelines
concerning the setting of administrative
fines referred to in Article 71.*

deleted

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Union Legislative Acts

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Amendment 114

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c a) support the Commission and the
Member States in the preparation of
guidance documents, including the
guidelines concerning the setting of
administrative fines referred to in Article
71;*

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain
Union Legislative Acts

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Amendment 115

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c b) encourage, facilitate and support
the drawing up of risk-commensurate
codes of conduct intended to foster the
voluntary application to AI systems of
those codes of conduct in close
cooperation with industry and other
relevant stakeholders in accordance with
Article 69;*

Or. en

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Amendment 116

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(c c) carry out periodic in-depth horizon-scanning, foresight, and market monitoring exercises to analyse trends and emerging issues in respect of this Regulation, with a particular focus on emerging technologies and their interaction with artificial intelligence, European global competitiveness in artificial intelligence, the uptake of artificial intelligence technologies, the development of digital skills, and emerging systemic threats related to artificial intelligence, including those referred to in Article 68a (1)(a) and (1)(b);

Or. en

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

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Amendment 117

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c d) cooperate with the European Data
Protection Board and with the FRA to
provide guidance in relation to the respect
of fundamental rights, in particular the
right to non-discrimination and to equal
treatment, the right to privacy and the
protection of personal data;*

Or. en

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

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Amendment 118

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c e) promote public awareness and
understanding of the benefits, risks, rules
and safeguards and rights in relation to
the use of AI systems;*

Or. en

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Amendment 119

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c f) promote the cooperation and
effective bilateral and multilateral
exchange of information and best
practices between the national supervisory
authorities;*

Or. en

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Amendment 120

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c g) facilitate cooperation between the
supervisory authorities of Member States
and other supervisory authorities that
might be responsible for the enforcement
of this Regulation;*

Or. en

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Union Legislative Acts

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Amendment 121

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c h) support capacity and expertise
building in supervisory authorities that
are responsible for the enforcement of
this Regulation;*

Or. en

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Amendment 122

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c i) advise the Commission on the
possible amendment of the Annexes by
means of delegated acts in accordance
with Article 73, in particular the annex
listing high-risk AI systems;*

Or. en

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Amendment 123

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c j) ensure that the national
supervisory authorities actively cooperate
in the implementation of this Regulation;*

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 124

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c k) adopt binding decisions for
national competent authorities in cases of
serious disagreements pursuant to article
59a (5);*

Or. en

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Amendment 125

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

***(c 1) promote the development of a
common European approach to
benchmarking by cooperating with
national metrology and benchmarking
authorities and by issuing opinions,
recommendations, written contributions,
or studies with a view to ensure consistent
and harmonised European benchmarking
standards;***

Or. en

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Amendment 126

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța,
Michal Šimečka**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

*(c m) provide guidance in relation to
children's rights, applicable law and
minimum standards to meet the objectives
of this Regulation that pertain to
children;*

Or. en

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Amendment 127

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

**(c n) promote and support the accessible
development and use of artificial
intelligence systems, in accordance with
the provisions of Directive (EU) 2019/882;**

Or. en

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Amendment 128

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa

Proposal for a regulation
Article 58 a (new)

Text proposed by the Commission

Amendment

Article 58 a

SECTION 3: the Executive Director

Functions and powers of the executive director

- 1. The AI Office shall be managed by its executive director, who shall be completely independent in the performance of his or her duties. Without prejudice to the respective competencies of the Union institutions and the management board, the executive director shall neither seek nor take instructions from any government or from any other body.***
- 2. The executive director may be called upon at any time by the European Parliament or by the Council to attend a***

hearing on any matter linked to the AI Office's activities or to report on the carrying out of his or her tasks. This includes reporting on the activities of the AI Office, the implementation of its annual programming, the annual activity report for the previous year, and any other matter related to the activities of the AO Office. The executive director shall also make a statement before the European Parliament, if requested, and shall answer in writing any question put forward by a Member of the European Parliament within 15 calendar days from receipt of such question. The executive director shall report regularly to the appropriate bodies and committees of the European Parliament.

3. Except where specific deadlines are provided for in this Regulation, the executive director shall ensure that reports are transmitted to the European Parliament, to the Council and to the Commission as soon as possible, and in any event within six months of the end of the reporting period, unless the executive director duly justifies a delay in writing.

4. The executive director shall be responsible for the preparation and implementation of the strategic decisions taken by the management board and for the taking of decisions related to the operational activities of the AI Office in accordance with this Regulation. The executive director shall have the following functions and powers:

(a) to propose, prepare and implement the strategic decisions and programmes and activities adopted by the management board within the limits set out in this Regulation, its implementing rules and any applicable law;

(b) to take all necessary steps, including the adoption of internal administrative instructions and the publication of

notices, to ensure the day-to-day administration and functioning of the AI Office in accordance with this Regulation;

(c) to prepare each year the draft single programming document pursuant to Article 57a (b) and to submit it to the management board for endorsement before that draft is sent to the European Parliament, to the Council and to the Commission;

(d) to draw up a draft statement of estimates of the revenues and expenditure of the AI Office as part of the single programming document pursuant to Article 57a (d) and to implement the budget of the AI Office;

(e) to prepare each year the annual activity report on the Agency's activities and submit it to the management board;

(f) to coordinate all staff matters and all matters of day-to-day administration of the AI Office;

(g) to prepare appropriate draft implementing rules to give effect to the Staff Regulations and the Conditions of Employment of Other Servants in accordance with Article 110 of the Staff Regulations;

(h) to protect the values and interests of the Union by drawing up, submitting to the management board for approval, and implementing effective internal anti-fraud, anti-corruption, data protection and equal opportunity strategies, procedures, and safeguards;

(i) to establish and implement effective monitoring and evaluation procedures relating to the performance of the AI Office against its objectives and to report annually to the management board on the results of the monitoring;

(j) to consult the advisory forum and to

facilitate its operations;

(k) to develop and maintain contact with industry, standardization bodies, academia, and civil society, including organizations protecting fundamental and digital rights, consumers, workers, children, persons with disabilities, and other vulnerable categories, to ensure regular dialogue with relevant stakeholders;

(l) to cooperate and to exchange views and information regularly with Union institutions, bodies, offices and agencies regarding artificial intelligence and related domains such as data, digital infrastructure, platform and internet governance, and cybersecurity, to ensure coherence in the development and the implementation of Union policy;

(m) to represent the AI Office in international fora for cooperation on Artificial Intelligence;

(n) To support the Chair of the management board in preparing and planning the management board meetings;

(o) to perform other tasks pursuant to this Regulation.

5. The executive director shall be accountable for his or her activities to the management board. 6. The executive director shall be the legal representative of the AI Office.

Or. en

EUROPEAN PARLIAMENT

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

01/06/2022

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

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

Amendment 129

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa

Proposal for a regulation
Article 58 b (new)

Text proposed by the Commission

Amendment

Article 58 b

SECTION 4: the Advisory Forum

The advisory forum

1. An advisory forum shall be established by the AI Office to advise it in the fulfilment of its tasks by providing stakeholder input in matters pertaining to this Regulation, in particular on:

(a) technological developments and trends related to artificial intelligence;

(b) potential updates of this Regulation, including prohibited practices, high-risk AI systems, AI systems requiring additional transparency obligations, and novel techniques used for the development of artificial intelligence;

(c) best practices to optimise compliance and to reduce compliance costs and regulatory burden;

(d) measures in support of innovation, start-ups, and SMEs, including improving participation in regulatory sandboxes;

(e) the development, promotion, and uptake of harmonised standards, harmonised benchmarking standards, and common specifications;

(f) emerging threats to health, safety, fundamental rights, or the values of the Union as enshrined in Article 2 TEU related to artificial intelligence;

2. The advisory forum shall have a balanced composition and represent the views of different stakeholders, with a third of its members representing industry, a third of its members representing start-ups, SMEs, and the innovation environment, and a third of its members representing civil society and academia.

3. Stakeholders established outside the Union shall only participate in the advisory forum if they are established in third countries that are subject to a decision of the Commission adopted in accordance with Article 36 of Directive (EU) 2016/680 or Article 45 of Regulation 2016/679 ('adequacy decision') or that are part of an international agreement concluded between the Union and that third country or international organisation pursuant to Article 218 TFEU adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals.

4. Members of the advisory forum shall be appointed by the management board, based on a recommendation from the executive director, following a transparent call for applications and selection

procedure.

5. When drawing up the call for applications and the selection procedure, the executive director shall ensure that:

(a) the composition criteria set out in paragraph 2 are met;

(b) the representation of industry, start-up, SMEs and the innovation environment is varied and includes stakeholders of different sizes and representing different industries;

(c) the representation of civil society is varied and includes, at a minimum, organizations for the protection of democracy, fundamental rights, consumer rights, the rights of persons with disabilities, and children's rights;

(d) the advisory forum is balanced in terms of geographical distribution and gender.

6. The term of office of the members of the advisory forum shall be two years. To ensure diversity and balanced representation, the term of office for members of the advisory forum shall not be renewable consecutively.

7. The advisory forum shall draw up its rules of procedure and elect three co-Chairs from among its members according to their presentation criteria set out in paragraph 2. Their term of office shall be two years, non-renewable.

8. The advisory forum shall hold regular meetings at least four times a year. The advisory forum can invite experts and other stakeholders to its meetings. The executive director can attend, ex officio, the meetings of the advisory forum.

9. In fulfilling its role as set out in paragraph 1, the advisory forum can prepare opinions, recommendations or written contributions and forward these to the attention of the executive director.

10. The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available, including on the AI Office website.

11. The AI Office shall provide secretarial assistance to the advisory forum to ensure its proper functioning.

Or. en

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Amendment 130

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation
Article 59 – paragraph 5

Text proposed by the Commission

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.

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 **AI Office** for discussion and possible recommendations.

Or. en

EUROPEAN PARLIAMENT

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Amendment 131

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Proposal for a regulation
Article 59 a (new)

Text proposed by the Commission

Amendment

Article 59 a

Cooperation mechanism between national supervisory authorities in cases involving two or more Member States

- 1. Each national supervisory authority shall perform its tasks and powers conferred on in accordance with this Regulation on the territory of its own Member State.*
- 2. In the event of a case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the provider or the user of the concerned AI system is established or where the authorised representative is appointed shall be considered to be the lead national*

supervisory authority.

3. In the cases referred to in paragraph 2, the relevant national supervisory authorities shall cooperate and exchange all relevant information in due time.

National supervisory authorities shall cooperate in order to reach a consensus.

4. In the case of a serious disagreement between two or more national supervisory authorities, the national supervisory authorities shall notify the AI Office and communicate without delay all relevant information related to the case to the AI Office.

5. The AI Office shall, within three months of receipt of the notification referred to in paragraph 4, issue a binding decision to the national supervisory authorities.

Or. en

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Amendment 132

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation
Article 64 – paragraph 2

Text proposed by the Commission

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.

Amendment

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, ***after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient***, and upon a reasoned request, the market surveillance authorities ***or, where applicable, the Commission***, shall be granted access to the source code of the AI system. ***Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.***

Or. en

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Amendment 133

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation
Article 65 – paragraph 3

Text proposed by the Commission

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.

Amendment

3. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission, **the AI Office** and the other Member States of the results of the evaluation and of the actions which it has required the operator to take.

Or. en

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Amendment 134

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons ***or*** to the compliance with obligations under Union or national law intended to protect fundamental rights, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk

as it may prescribe.

Or. en

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Amendment 135

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 67 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *Should the provider or other relevant operators fail to take corrective action as referred to in paragraph 2 and should the AI system continue to present a risk as referred to in paragraph 1, the market surveillance authority may require the relevant operator, as a measure of last resort, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk.*

Or. en

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Amendment 136

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation
Article 67 – paragraph 3

Text proposed by the Commission

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Amendment

3. The Member State shall immediately inform the Commission, *the AI Office*, and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Or. en

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Amendment 137
Dragoş Tudorache

Proposal for a regulation
Article 69 – paragraph 1

Text proposed by the Commission

1. The Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the *voluntary application to* AI systems other than high-risk AI systems of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

Amendment

1. The Commission, *AI Office*, and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the *development and use of safe and trustworthy AI for* AI systems other than high-risk AI systems. *These codes of conduct should be voluntary and should be based on* 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 *but be adapted* in light of the intended purpose of the systems *and of the lower risk involved*

Or. en

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Amendment 138

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța

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. The Commission and the **AI Office** 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.

Or. en

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

Amendment 139
Dragoş Tudorache

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

Or. en

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Amendment 140

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța**

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 **AI Office** 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.

Or. en

EUROPEAN PARLIAMENT

*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 141

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. ***The Commission, the AI Office,*** national ***competent*** competent authorities and notified bodies involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Or. en

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Amendment 142

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation Article 71 – paragraph 1

Text proposed by the Commission

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale providers and *start-up* and their economic viability.

Amendment

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests *and size* of small-scale providers and *start-ups* and their economic viability.

Or. en

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Amendment 143

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

Article 71 – paragraph 3 – introductory part

Text proposed by the Commission

3. ***The following infringements*** shall be subject to administrative fines of up to **30 000 000 EUR** or, if the offender is company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Amendment

3. ***Non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** shall be subject to administrative fines of up to **30 000 000EUR** or, if the offender is **a** company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher;

Or. en

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Amendment 144

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten
Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 71 – paragraph 3 – point a

Text proposed by the Commission

Amendment

*(a) non-compliance with the
prohibition of the artificial intelligence
practices referred to in Article 5;*

deleted

Or. en

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Amendment 145

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Svenja Hahn, Morten
Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 71 – paragraph 3 – point b

Text proposed by the Commission

Amendment

*(b) non-compliance of the AI system
with the requirements laid down in Article
10.*

deleted

Or. en

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Amendment 146

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Proposal for a regulation

Article 71 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

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Amendment 147

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Proposal for a regulation
Article 71 – paragraph 4

Text proposed by the Commission

4. **The** non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **20 000 000** EUR or, if the offender is a company, up to **4** % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Amendment

4. Non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **10 000 000** EUR or, if the offender is a company, up to **2** % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Or. en

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Amendment 148

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 71 – paragraph 7

Text proposed by the Commission

7. Each Member State shall **lay down** rules on **whether and to what extent** administrative fines **may** be imposed on public authorities and bodies established in that Member State.

Amendment

7. Each Member State shall **laydown** rules on administrative fines **to** be imposed on public authorities and bodies established in that Member State, **with a view to ensure compliance with this Regulation.**

Or. en

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Amendment 149

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Alin Mituţa**

Proposal for a regulation

Article 72 – paragraph 2 – introductory part

Text proposed by the Commission

2. ***The following infringements*** shall
be subject to administrative fines of up to
500 000 EUR:

Amendment

2. ***Non-compliance with the
prohibition of the artificial intelligence
practices referred to in Article 5*** shall be
subject to administrative fines of up to
1.000 000EUR;

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Amendment 150

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 72 – paragraph 2 – point a

Text proposed by the Commission

Amendment

*(a) non-compliance with the
prohibition of the artificial intelligence
practices referred to in Article 5;*

deleted

Or. en

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*Committee on the Internal Market and Consumer Protection, Committee on Civil Liberties,
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Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain
Union Legislative Acts

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

Amendment 151

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 72 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) non-compliance of the AI system with the requirements laid down in Article 10. *deleted*

Or. en

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Amendment 152

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Proposal for a regulation

Article 72 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 500 000 EUR.

Or. en

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Amendment 153

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Proposal for a regulation
Article 72 – paragraph 3

Text proposed by the Commission

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **250 000** EUR.

Amendment

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to **300 000** EUR.

Or. en

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Amendment 154

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation

Article 73 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Prior to adopting a delegated act pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6), and Article 48(5) the Commission shall consult the AI Office.

Or. en

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Amendment 155

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituța**

Proposal for a regulation

Article 73 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

***3 b. Delegated acts that lead to the
modification or the addition of obligations
on operators shall foresee an adequate
transition period of no less than 24
months before their entry into force.***

Or. en

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Amendment 156

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Proposal for a regulation
Article 73 – paragraph 4

Text proposed by the Commission

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament *and to* the Council.

Amendment

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament, the Council, *and the AI Office*.

Or. en

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Amendment 157

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Proposal for a regulation

Article 82 a (new)

Text proposed by the Commission

Amendment

Article 82 a

Sound regulation

In taking into account the requirements of this Regulation pursuant to the Amendments in Articles 75, 76, 77, 78, 79, 80, 81, and 82, the Commission shall conduct an analysis and consult relevant stakeholders to determine potential gaps as well as overlaps between existing sectoral legislation and the provisions of this Regulation in order to avoid duplication, overregulation, and the creation of loopholes.

Or. en

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Amendment 158

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. ***This Regulation shall not apply to*** the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [***12 months after*** the date of application of this Regulation referred to in Article 85(2)], ***unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.***

Amendment

1. ***Operators of*** the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [the date of application of this Regulation referred to in Article 85(2)] ***shall take the necessary steps to comply with the requirements of the present Regulation within 4 years of its entry into force.***

Or. en

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Amendment 159

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Proposal for a regulation

Article 83 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Amendment

The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts ***and whenever those legal acts are replaced or amended.***

Or. en

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Amendment 160

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 83 – paragraph 2

Text proposed by the Commission

2. ***This Regulation shall apply to the*** high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], ***only if, from that date, those*** systems are subject to ***significant changes*** in their design or intended purpose.

Amendment

2. ***Operators of*** high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)] ***shall take the necessary steps to comply with the requirements of the present Regulation within 2 years of its entry into force or at the time when such*** systems are subject to ***a substantial modification*** in their design or intended purpose.

Or. en

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Amendment 161

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation
Article 84 – paragraph 1

Text proposed by the Commission

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

Amendment

1. ***In consultation with the AI Office, the Commissions shall*** assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.

Or. en

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Amendment 162

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Article 84 – paragraph 3 – point b

Text proposed by the Commission

(b) the state of penalties, and notably administrative fines as referred to in Article **71(I)**, applied by Member States to infringements of the provisions of this Regulation.

Amendment

(b) the state of penalties, and notably administrative fines as referred to in Article **71**, applied by Member States to infringements of the provisions of this Regulation.

Or. en

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Amendment 163

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn,
Morten Løkkegaard, Alin Mituţa**

Proposal for a regulation

Article 84 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

***(b a) the state of the development of
harmonised standards and common
specifications for Artificial Intelligence;***

Or. en

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Amendment 164

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation
Article 84 – paragraph 4

Text proposed by the Commission

4. Within [**three years** after the date of application of this Regulation referred to in Article 85(2)] and every **four** years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.

Amendment

4. Within [**one year** after the date of application of this Regulation referred to in Article 85(2)] and every **two** years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.

Or. en

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Amendment 165

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituţa**

Proposal for a regulation
Article 84 – paragraph 5

Text proposed by the Commission

5. For the purpose of paragraphs 1 to 4 the **Board**, the Member States and national competent authorities shall provide the Commission with information on its request.

Amendment

5. For the purpose of paragraphs 1 to 4 the **AI Office**, the Member States and national competent authorities shall provide the Commission with information on its request.

Or. en

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Amendment 166

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Proposal for a regulation
Article 84 – paragraph 6

Text proposed by the Commission

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the **Board**, of the European Parliament, of the Council, and of other relevant bodies or sources.

Amendment

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of the **AI Office**, of the European Parliament, of the Council, and of other relevant bodies or sources.

Or. en

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Amendment 167

**Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu,
Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

Annex III – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

1. Biometric identification *and*
categorisation of natural persons:

Amendment

1. **1. Biometric and biometrics-based
systems:**

*(a) AI systems intended to be used for the
'real-time' and 'post' remote biometric
identification of natural persons;*

*(b) AI systems intended to be used for the
remote biometric categorisation of natural
persons in publicly-accessible spaces;*

*(c) AI systems intended to be used for
emotion recognition in natural persons;*

Or. en

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Amendment 168
Dragoş Tudorache

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

Text proposed by the Commission

Amendment

(a) *AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons;* *deleted*

Or. en

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Amendment 169

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Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța**

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 170

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

Annex III – paragraph 1 – point 4 – point b

Text proposed by the Commission

(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, *for* task allocation and for monitoring and evaluating performance and *behavior of* persons in such relationships.

Amendment

(b) AI *systems* intended to be used for *making decisions or to assist in* making decisions on promotion and termination of work-related contractual relationships; *for personalized* task allocation *based on biometrics, biometrics-based, or personal data*; and for monitoring and evaluating performance and *behaviour of natural* persons in such relationships.

Or. en

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Amendment 171

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Proposal for a regulation

Annex III – paragraph 1 – point 5 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 172

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Proposal for a regulation

Annex III – paragraph 1 – point 6 – point b

Text proposed by the Commission

(b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Amendment

(b) AI systems intended to be used by ***law enforcement authorities or on behalf of*** law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

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Amendment 173

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Proposal for a regulation

Annex III – paragraph 1 – point 6 – point c

Text proposed by the Commission

(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);

Amendment

(c) AI systems intended to be used by ***law enforcement authorities or on behalf of*** law enforcement authorities to detect deep fakes as referred to in article 52(3);

Or. en

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Amendment 174

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Proposal for a regulation

Annex III – paragraph 1 – point 6 – point d

Text proposed by the Commission

(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Amendment

(d) AI systems intended to be used by ***law enforcement authorities or on behalf of*** law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;

Or. en

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Amendment 175

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Proposal for a regulation

Annex III – paragraph 1 – point 6 – point f

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 176

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point a

Text proposed by the Commission

(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

Amendment

(a) AI systems intended to be used by competent public authorities *or on their behalf* as polygraphs and similar tools or to detect the emotional state of a natural person;

Or. en

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Amendment 177

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Proposal for a regulation

Annex III – paragraph 1 – point 7 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

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

Amendment 178

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Svenja Hahn, Alin Mituța**

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point c

Text proposed by the Commission

(c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Amendment

(c) AI systems intended to be used by competent public authorities ***or on their behalf*** for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

Or. en

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Amendment 179

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Svenja Hahn, Alin Mituţa**

Proposal for a regulation

Annex III – paragraph 1 – point 7 – point d

Text proposed by the Commission

(d) AI systems intended to assist competent public authorities *for* the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Amendment

(d) AI systems intended *to be used by competent public authorities or on their behalf or* to assist competent public authorities *in* the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

Or. en

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Amendment 180

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Alin Mituța**

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a

Text proposed by the Commission

(a) AI systems intended to assist a
judicial authority in researching and
interpreting facts *and* the law and in
applying the law to a concrete set of facts.

Amendment

(a) AI systems intended *to be used by a
judicial authority or administrative body
or on their behalf or* to assist a judicial
authority *or administrative body* in
researching and interpreting facts *or* the
law and in applying the law to a concrete
set of facts.

Or. en

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Amendment 181

**Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu,
Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior,
Alin Mituța**

Proposal for a regulation

Annex III – paragraph 1 – point 8 – point a a (new)

Text proposed by the Commission

Amendment

*(a a) AI systems used by political
parties, political candidates, public
authorities, or on their behalf for
influencing natural persons in the
exercise of their vote in local, national, or
European Parliament elections;*

Or. en

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Amendment 182

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Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa**

Proposal for a regulation

Annex III – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

8 a. Other applications:

(a) AI systems intended to be used to generate, on the basis of limited human input, complex text content that would falsely appear to a person to be human generated and authentic, such as news articles, opinion articles, novels, scripts, and scientific articles, with the exception of AI systems used exclusively for content that undergoes human review and for the publication of which a natural or legal person established in the Union is liable or holds editorial responsibility;

(b) AI systems intended to be used to generate or manipulate audio or video content that features existing natural persons appearing to say or do something they have never said or done, with the

*exception of AI systems used exclusively
for content that forms part of an evidently
artistic, creative or fictional
cinematographic and analogous work;*

*(c)AI systems that deploy subliminal
techniques for scientific research and for
therapeutical purposes;*

Or. en

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Amendment 183

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Proposal for a regulation

Annex IV – paragraph 1 – point 5

Text proposed by the Commission

5. A description of any change made to the system through its lifecycle;

Amendment

5. A description of any **relevant** change made to the system through its lifecycle;

Or. en

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Amendment 184

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Proposal for a regulation

Annex VII – point 4 – point 4.5

Text proposed by the Commission

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system.

Amendment

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, ***after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient***, and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system. ***Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.***

Or. en

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Amendment 185

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Róza Thun und Hohenstein, Alin Mituța

Proposal for a regulation

Annex VIII – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The following information shall be provided and updated with regard to high risk AI systems to be registered in accordance with Article 51(2) by users who are or act on behalf of public authorities or Union institutions, bodies, offices or agencies:

- 1. the name, address and contact details of the user;***
- 2. the name, address and contact details of any person submitting information on behalf of the user;***
- 3. the high-risk AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system used;***

4. a description of the intended use of the AI system, including the specific outcomes sought through the use of the system;

5. a summary of the findings of the fundamental rights impact assessment conducted in accordance with the obligation of public authorities or Union institutions, agencies, offices or bodies set out in this Regulation;

6. a summary of the data protection impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 as specified in paragraph 6 of Article 29 of this Regulation, where applicable; 6. a declaration of conformity with the applicable data protection rules.

Or. en