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

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AMENDMENTS
539 - 773

Draft report
Brando Benifei, Dragoş Tudorache
(PE731.563v01-00)

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

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

Amendment 539
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 32

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

Or. en

Amendment 540
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) As regards stand-alone AI systems, meaning high-risk AI systems other than those that are safety components of products, or which are themselves	(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.

products, it is appropriate to classify them as high-risk if, in the light of their intended purpose ***or reasonably foreseeable uses***, 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.

(This amendment should apply throughout the text, i.e. any occurrence of "intended purpose" should be followed by "or reasonably foreseeable uses")

Or. en

Amendment 541
Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation
Recital 32

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

Or. en

Amendment 542
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 32

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

Or. en

Amendment 543
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 32 a (new)

Text proposed by the Commission	*Amendment*
	(32 a) In the light of the nature and complexity of the value chain for AI systems, it is essential to consider the foreseeable high-risks they can create when combined. Particular attention should be paid to the foreseeable uses and

reasonably foreseeable misuses of AI systems with indeterminate uses.

Or. en

Amendment 544
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Recital 33

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

Or. en

Justification

Moved under prohibited practices

Amendment 545
Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Marc Angel

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies of AI systems intended for the remote biometric	***deleted***

identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Or. en

Amendment 546
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.	(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk***, except for verification or authentification systems whose sole purpose is to confirm that a specific natural person is the person he or she claims to be, and systems that are used to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises***. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.

Or. en

Amendment 547
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.	(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be classified as high-risk***, except for the purpose of remote client on-boarding or verification of a user through a device***. In view of the risks that they ***may*** pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and***, when appropriate and justified by a proven added value to the protection of health, safety and fundamental rights,*** human oversight.

Or. en

Amendment 548
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be	(33) Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. Therefore, 'real-time' and 'post' remote biometric identification systems should be

classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight.	classified as high-risk. In view of the risks that they ***may*** pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and***, when appropriate and justified by a proven added value to the protection of health, safety and fundamental rights,*** human oversight.

Or. en

Amendment 549
Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation
Recital 33

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

Or. en

Amendment 550
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 33

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

Or. en

Amendment 551
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä, Patrick Breyer, Marcel Kolaja
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Technical inaccuracies ***of*** AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. ***Therefore***, 'real-time' and 'post' remote biometric identification systems ***should be classified as high-risk. In view of the risks that they pose, both types of remote biometric identification systems should be subject to specific requirements on logging capabilities and human oversight***.	(33) Technical inaccuracies***, as well as conscious or subconscious design decisions, and the use of training data which codify and reinforce structural inequalities, mean that*** AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. This is particularly relevant when it comes to age, ethnicity, sex or disabilities. ***As a result***, 'real-time' and 'post' remote biometric identification systems ***undermine the essence of fundamental rights and therefore must be prohibited***.

Or. en

Amendment 552

Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 33 a (new)

Text proposed by the Commission	*Amendment*
	(33 a) Human oversight should target high-risk AI systems as a priority, with the aim of serving human-centric objectives. The individuals to whom human oversight is assigned shall be provided with adequate education and training on the functioning of the application, its capabilities to influence or make decisions, and to have harmful effects, notably on fundamental rights. The persons in charge of the assignment of these individuals shall provide them with relevant staff and psychological support.

Or. en

Amendment 553
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 34

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

Or. en

Amendment 554
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Andrus Ansip, Dita Charanzová, Alin Mituța, Michal Šimečka

Proposal for a regulation
Recital 34

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

Or. en

Amendment 555
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 34

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

Or. fr

Amendment 556
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination.	(35) AI systems used in education or vocational training, notably for determining access or assigning persons to educational and vocational training institutions or to evaluate persons on tests as part of or as a precondition for their education should be considered high-risk, since they may determine the educational and professional course of a person's life and therefore affect their ability to secure their livelihood. When improperly designed and used, such systems may violate the right to education and training as well as the right not to be discriminated against and perpetuate historical patterns of discrimination. ***Therefore, AI systems in education shall be prohibited to be used by public authorities in education of underaged children to meet the requirement in this regulation, to not exploit any of the vulnerabilities of the group of persons due to their age.***

Or. en

Amendment 557
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) AI systems used in education or vocational training, notably for	(35) AI systems used in education or vocational training, notably for

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

Or. en

Amendment 558
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 35

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

Or. fr

Amendment 559
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 35

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

Or. en

Amendment 560
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) AI systems used in employment, workers management and access to self-employment, notably ***for the*** recruitment and selection of persons, for making decisions on promotion and ***termination and*** for task allocation, monitoring ***or*** evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems	(36) AI systems used in employment, workers management and access to self-employment, notably ***affecting the initiation, establishment, implementation and termination of an employment relationship, including AI systems intended to support collective legal and regulatory matters should be high risk. Particularly AI affecting*** recruitment and

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

selection of persons, for making decisions on promotion and for task allocation, ***for measuring and*** monitoring ***of performance or for*** 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. ***AI systems used for constant monitoring of workers pose an unacceptable risk to their fundamental rights, and should be therefore prohibited.*** Relevant work-related contractual relationships should ***meaningfully*** involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. 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 ***undermine the essence of*** their ***fundamental*** rights to data protection and privacy. ***This Regulation applies without prejudice to Union and Member State competences to provide for more specific rules for the use of AI-systems in the employment context.***

Or. en

Amendment 561
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) AI systems used in employment,	(36) AI systems used in employment,

workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may perpetuate historical patterns of discrimination, for example against women, certain age groups, persons with disabilities, or persons of certain racial or ethnic origins or sexual orientation. AI systems used to monitor the performance and behaviour of these persons may also impact their rights to data protection and privacy.

workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for ***personalised*** task allocation ***based on personal 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 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

Amendment 562
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or	(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or

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

evaluation of persons in work-related contractual relationships, should also be classified as high-risk, ***in so far as such use does not correspond to practices prohibited by this Regulation,*** since those systems may appreciably impact future career prospects and livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through platforms as referred to in the Commission Work Programme 2021. Such persons should in principle not be considered users within the meaning of this Regulation. Throughout the recruitment process and in the evaluation, promotion, or retention of persons in work-related contractual relationships, such systems may ***lead to*** 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. fr

Amendment 563
Svenja Hahn, Nicola Beer, Karen Melchior, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Recital 36

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

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

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

Or. en

Amendment 564
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons, for making decisions on promotion and termination and for task allocation, monitoring or evaluation of persons in work-related contractual relationships, should also be classified as high-risk, since those systems ***may appreciably*** impact future career prospects ***and*** livelihoods of these persons. Relevant work-related contractual relationships should involve employees and persons providing services through	(36) AI systems used in employment, workers management and access to self-employment, notably ***but not limited to,*** 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 impact future career prospects***,*** livelihoods of these persons ***and workers' rights***. Relevant work-related contractual relationships should involve employees and persons providing services

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

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Or. en

Amendment 565
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 36

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

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.	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

Amendment 566
Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation
Recital 36 a (new)

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

Or. en

Amendment 567
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 36 b (new)

Text proposed by the Commission	*Amendment*
	(36 b) Given the significance of Artificial Intelligence impact assessments according to the usage Artificial Intelligence applications in the workplace, the EU will consider a corresponding directive with specific provisions for an impact assessment to ensure the protection of the

rights and freedoms of workers affected by AI systems through collective agreements of national legislation.

Or. en

Amendment 568
Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used ***for this purpose*** may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems ***that automatically generate models*** used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. ***In contrast, ancillary applications to those systems determining whether an individual should be granted access to credit, such as AI applications used for the acceleration of the credit disbursement process, in the valuation of collateral, or for the internal process efficiency, as well as other subsequent applications based on the credit scoring which do not create high risks for individuals should be exempt from the scope.*** AI systems used ***to evaluate the credit score or creditworthiness*** may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of

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

Or. en

Amendment 569
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 37

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

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

Or. en

Amendment 570
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be ***classified as high-risk AI systems***, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be ***prohibited***, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services

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

from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 571
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems

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

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

persons and their property.

Or. en

Amendment 572
Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied,	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use***. Due to the fact that AI systems related to low-value credits for the purchase of movables do not cause high risk, it is proposed to exclude this category from the scope of high-risk AI category as well.*** . Natural persons applying for or receiving public assistance benefits and services from public authorities are typically

reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 573
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems ***that automatically generate models*** used to evaluate the credit score or creditworthiness of natural persons should

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

be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. ***In contrast, ancillary applications to those systems determining whether an individual should be granted access to credit, such as AI applications used for the acceleration of the credit disbursement process, in the valuation of collateral, or for the internal process efficiency, as well as other subsequent applications based on the credit scoring which do not create high risks for individuals should be exempt from the scope.*** AI systems used ***to evaluate the credit score or creditworthiness*** may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. ***In fact***, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should

also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 574
Kosma Złotowski, Patryk Jaki, Eugen Jurzyca

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use. Natural persons applying for or receiving public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by small-scale providers for their own use***. Due to the fact that AI systems related to low-value credits for the purchase of moveables does not cause high risk, it is proposed to exclude this category from the scope of high-risk AI category as well***. Natural persons applying for or receiving

are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.	public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 575
Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or

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

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

over to computer systems.

Or. fr

Justification

The ban on AI systems used to dispatch or establish priority in the dispatching of emergency first response services shall apply only to those systems that make decisions on such matters not to those that provide mere recommendations.

Amendment 576
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Catharina Rinzema, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by ***small-scale providers*** for their own use. Natural persons applying for or receiving	(37) Another area in which the use of AI systems deserves special consideration is the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living. In particular, AI systems used to evaluate the credit score or creditworthiness of natural persons should be classified as high-risk AI systems, since they determine those persons' access to financial resources or essential services such as housing, electricity, and telecommunication services. AI systems used for this purpose may lead to discrimination of persons or groups and perpetuate historical patterns of discrimination, for example based on racial or ethnic origins, disabilities, age, sexual orientation, or create new forms of discriminatory impacts. Considering the very limited scale of the impact and the available alternatives on the market, it is appropriate to exempt AI systems for the purpose of creditworthiness assessment and credit scoring when put into service by ***SMEs and start-ups*** for their own use. Natural persons applying for or receiving

public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

public assistance benefits and services from public authorities are typically dependent on those benefits and services and in a vulnerable position in relation to the responsible authorities. If AI systems are used for determining whether such benefits and services should be denied, reduced, revoked or reclaimed by authorities, they may have a significant impact on persons' livelihood and may infringe their fundamental rights, such as the right to social protection, non-discrimination, human dignity or an effective remedy. Those systems should therefore be classified as high-risk. Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons. Finally, AI systems used to dispatch or establish priority in the dispatching of emergency first response services should also be classified as high-risk since they make decisions in very critical situations for the life and health of persons and their property.

Or. en

Amendment 577
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37 a) Given the speed at which AI applications are being developed around the world, it is not feasible to compile an exhaustive listing of applications that should be prohibited or considered high-risk. What is needed is a clear and coherent governance model guaranteeing

both the fundamental rights of individuals and legal clarity for operators, considering the continuous evolution of technology. Nevertheless, given the role and responsibility of police and judicial authorities, and the impact of decisions they take for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, the use of AI applications has to be categorised as high-risk in instances where there is the potential to significantly affect the lives of individuals.

Or. en

Amendment 578
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not	(38) Actions by law enforcement authorities involving certain uses of AI systems are characterised by a significant degree of power imbalance and may lead to surveillance, arrest or deprivation of a natural person's liberty as well as other adverse impacts on fundamental rights guaranteed in the Charter. In particular, if the AI system is not trained with high quality data, does not meet adequate requirements in terms of its accuracy or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner. ***In addition, some applications, such as to make predictions, profiles, or risk assessments based on data analysis or profiling of groups or individuals for the purpose of predicting the occurrence or recurrence of actual or potential offences or rule-***

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.***

breaking undermine the essence of fundamental rights and should be prohibited. 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 ***prohibited*** a number of AI systems intended to be used in the law enforcement context as well as for crime analytics regarding natural persons.

Or. en

Amendment 579
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Recital 38

Text proposed by the Commission *Amendment*

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

(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 performance, including*** 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. 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.

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

Amendment 580
Jean-Lin Lacapelle, Markus Buchheit, Hélène Laporte

Proposal for a regulation
Recital 38

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

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.

occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons or to assess personality traits of natural persons or groups for profiling in the course of detection, investigation or prosecution of criminal offences, shall be prohibited except in the three specific cases provided for in this Regulation. AI systems ***other than the aforementioned and*** intended to be used in ***a*** law enforcement context where accuracy, reliability and transparency is particularly important ***shall be classed as high-risk AI systems*** 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, to detect 'deep fakes', for the evaluation of the reliability of evidence in criminal proceedings, or assessing characteristics or past criminal behaviour of natural persons or groups for profiling in the course of detection, investigation or prosecution of criminal offences, as well as for crime analytics regarding natural persons. AI systems specifically intended to be used for administrative proceedings by tax and customs authorities should not be considered high-risk AI systems used by law enforcement authorities for the purposes of prevention, detection, investigation and prosecution of criminal offences.

Or. fr

Amendment 581
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 38

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

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.	offences.

Or. en

Justification

Moved to prohibitions.

Amendment 582
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Samira Rafaela, Monica Semedo, Salima Yenbou, Abir Al-Sahlani, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Recital 38

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

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

Justification

Predictive policing moved to prohibited practices.

Amendment 583
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen Melchior,

Svenja Hahn, Alin Mituța

Proposal for a regulation
Recital 38

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

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.

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

Amendment 584
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 38

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

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

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

Or. en

Amendment 585
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission	*Amendment*

(38 a) The use of AI tools by law enforcement and judicial authorities should not become a factor of inequality, social fracture or exclusion. The impact of the use of AI tools on the defence rights of suspects should not be ignored, notably the difficulty in obtaining meaningful information on their functioning and the consequent difficulty in challenging their results in court, in particular by individuals under investigation.

Or. en

Amendment 586
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. ***It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum; for verifying the authenticity of***	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation.

the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation.

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

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

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

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

Or. en

Amendment 587
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and

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

transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation.

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

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

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

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

Amendment 588
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management ***as polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or applying for visa or asylum***; for verifying the authenticity of the relevant documents of natural persons; ***for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status.*** AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the	(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the competent public authorities charged with tasks in the fields of migration, asylum and border control management; for verifying the authenticity of the relevant documents of natural persons; AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council, the Regulation (EC) No 810/2009 of the European Parliament and of the Council and other relevant legislation.

relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation.

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

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

Or. en

Amendment 589
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä, Tineke Strik
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) AI systems used in migration, asylum and border control management affect people who are often in particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the	(39) AI systems used in migration, asylum and border control management affect people who are often in ***a*** particularly vulnerable position and who are dependent on the outcome of the actions of the competent public authorities. The accuracy, non-discriminatory nature and transparency of the AI systems used in those contexts are therefore particularly important to guarantee the respect of the fundamental rights of the affected persons, notably their rights to free movement, non-discrimination, protection of private life and personal data, international protection and good administration. It is therefore appropriate to classify as high-risk AI systems intended to be used by the

competent public authorities charged with tasks in the fields of migration, asylum and border control management as ***polygraphs and similar tools or to detect the emotional state of a natural person; for assessing certain risks posed by natural persons entering the territory of a Member State or*** applying for visa or asylum; for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council[49] , the Regulation (EC) No 810/2009 of the European Parliament and of the Council[50] and other relevant legislation***.***

competent public authorities charged with tasks in the fields of migration, asylum and border control management as applying for visa or asylum; for verifying the authenticity of the relevant documents of natural persons; for assisting competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the objective to establish the eligibility of the natural persons applying for a status. AI systems in the area of migration, asylum and border control management covered by this Regulation should comply with the relevant procedural requirements set by the Directive 2013/32/EU of the European Parliament and of the Council, the Regulation (EC) No 810/2009 of the European Parliament and of the Council and other relevant legislation

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

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

Or. en

Amendment 590
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*

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

[49] Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection

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

[49] Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection

(OJ L 180, 29.6.2013, p. 60).	(OJ L 180, 29.6.2013, p. 60).
[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).	[50] Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1).

Or. fr

Amendment 591
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä, Tineke Strik
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 592
Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*

	(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 593
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 594
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39 a) The use of AI systems in migration, asylum and border control management should in no circumstances be used by Member States or European Union institutions as a means to circumvent their international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January1967, nor should they be used to in any way infringe on the principle of non-refoulement, or deny safe and effective legal avenues into the territory of the Union, including the right to international protection;

Or. en

Amendment 595
Abir Al-Sahlani, Svenja Hahn, Samira Rafaela, Monica Semedo

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39 a) The use of AI systems in migration, asylum and border management should however not, at any point, be used by Member States or by the institutions or agencies of the Union to infringe on the principle of non-refoulement, the right to asylum or to circumvent international obligations under the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967.

Or. en

Amendment 596
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law ***to a concrete set of facts***. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources**.**	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. ***The use of Artificial Intelligence tools can support, but should not interfere with the decision-making power of judges or judicial independence, as the final decision-making must remain a human-driven activity and decision.*** In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources

Or. en

Amendment 597
Vincenzo Sofo, Kosma Złotowski

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*

(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching ***and interpreting*** facts and the law ***and in applying the law to a concrete set of facts***. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in researching facts and the law. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Or. en

Amendment 598
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) Certain AI systems intended for the administration of justice and democratic processes should be ***classified as high-risk***, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to ***qualify as high-risk*** AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law to a concrete set of facts. Such qualification should not	(40) Certain AI systems intended for the administration of justice and democratic processes should be ***prohibited***, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to ***prohibit the use of*** AI systems intended to assist judicial authorities in researching and interpreting facts and the law and in applying the law to a concrete set of facts. Such qualification should not extend,

extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.	however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Or. fr

Amendment 599
Svenja Hahn, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in ***researching and*** interpreting facts ***and*** the law ***and in*** applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.	(40) Certain AI systems intended for the administration of justice and democratic processes should be classified as high-risk, considering their potentially significant impact on democracy, rule of law, individual freedoms as well as the right to an effective remedy and to a fair trial. In particular, to address the risks of potential biases, errors and opacity, it is appropriate to qualify as high-risk AI systems intended to assist judicial authorities in interpreting facts ***or*** the law ***for*** applying the law to a concrete set of facts. Such qualification should not extend, however, to AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources.

Or. en

Amendment 600
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40 a) Another area in which the use of AI systems deserves special consideration is the use for health-related purposes, including healthcare. Next to medical devices (as per EU regulation 2017/745), other health-related AI systems also bring about risks which should be regulated. These include systems that influence individual's health outcomes but do not meet the criteria for a medical device, systems that influence population health outcomes or health equality, systems that impact the distribution of healthcare resources and systems used by pharmaceutical and medical technology companies in research and development, pharmacovigilance, market optimisation and pharmaceutical marketing. Bias and errors in health-related AI systems can have major and immediate consequences for individuals' and populations' health and wellbeing. Further, many systems will use sensitive and personal data, which needs to be justified, and about which patients need to be properly informed. What is more, systems that work on hospital, health system, or population level may have a major effect on societal health because they influence the distribution of healthcare resources and health policy design. For these reasons, there is a need for trustworthy AI in healthcare, meaning people must be able to trust that systems used in healthcare are scientifically, technically and clinically valid, safe and accountable, and safeguard individuals' autonomy and privacy.

Or. en

Amendment 601
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40 a) Certain AI systems should at the same time be subject to transparency requirements and be classified as high-risk AI systems, given their potential to deceive and cause both individual and societal harm. In particular, AI systems that generate deep fakes representing existing persons have the potential to both manipulate the natural persons that are exposed to those deep fakes and harm the persons they are representing or misrepresenting, while AI systems that, based on limited human input, generate complex text such as news articles, opinion articles, novels, scripts and scientific articles have the potential to manipulate, to deceive, or to expose natural persons to built-in biases or inaccuracies. These should not include AI systems intended to translate text, or cases where the content forms part of an evidently artistic, creative or fictional cinematographic and analogous work.

Or. en

Amendment 602
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

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

Amendment 603
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40 a) Certain AI-systems used in the area of healthcare that are not covered by Regulation (EU) 2017/745 (Regulation on Medical Devices) should be high-risk. Uses such as software impacting diagnostics, treatments or medical prescriptions and access to health insurance can clearly impact health and safety, but also can also obstruct access to health services, impact the right to health care and cause physical harm in the long run.

Or. en

Amendment 604
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*

(40 a) Transparency requirements shall not apply where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme.

Or. en

Amendment 605
Morten Løkkegaard

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40 a) Transparency requirements shall not apply where the content forms part of an evidently artistic, creative, satirical, fictional and analogous work or programme.

Or. en

Amendment 606
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

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

Amendment 607
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 40 b (new)

Text proposed by the Commission	*Amendment*
	(40 b) Certain AI-systems used in the area of media, particularly in the area of social media, due to their potentially large reach and the specific risk of large scale spread of disinformation and exacerbation of societal polarisation should be high-risk due to their potential impact on individuals' rights, but also on society and democracy at large.

Or. en

Amendment 608
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is	(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is

necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data***, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons***. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data***, where relevant***.	necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data.

Or. en

Amendment 609
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data***, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons***. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where	(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.

relevant.

Or. en

Amendment 610
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data***, *on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons***. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.	(41) The fact that an AI system is classified as high risk under this Regulation should not be interpreted as indicating that the use of the system is necessarily lawful under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.

Or. en

Amendment 611
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) The fact that an AI system is ***classified as high risk*** under this	(41) The fact that an AI system is ***compliant with the requirements for high-***

Regulation should not be interpreted as indicating that the use of the system is necessarily ***lawful*** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. This Regulation ***should not*** be understood as providing for the legal ground for processing of personal data***, including special categories of personal data,*** where relevant.	***risk AI*** under this Regulation should not be interpreted as indicating that the use of the system is necessarily ***unlawful*** under other acts of Union law or under national law compatible with Union law, such as on the protection of personal data, on the use of polygraphs and similar tools or other systems to detect the emotional state of natural persons. Any such use should continue to occur solely in accordance with the applicable requirements resulting from the Charter and from the applicable acts of secondary Union law and national law. ***As far as is applicable and proportionate,*** this Regulation ***may, where duly justified,*** be understood as providing for the legal ground for processing of personal data where relevant.

Or. en

Amendment 612
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41 a) AI systems do not operate in a lawless world. A number of legally binding rules at European, national and international level already apply or are relevant to AI systems today. Legal sources include, but are not limited to EU primary law (the Treaties of the European Union and its Charter of Fundamental Rights), EU secondary law (such as the General Data Protection Regulation, the Product Liability Directive, the Regulation on the Free Flow of Non-Personal Data, anti-discrimination Directives, consumer law and Safety and Health at Work Directives), the UN Human Rights treaties and the Council of Europe conventions (such as the European Convention on Human Rights), and numerous EU Member State laws.

Besides horizontally applicable rules, various domain-specific rules exist that apply to particular AI applications (such as for instance the Medical Device Regulation in the healthcare sector).

Or. en

Amendment 613
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş 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	*Amendment*
(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider.	(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose of the use of the system and according to the risk management system to be established by the provider. ***These requirements should be objective-driven, fit to purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators.***

Or. en

Amendment 614
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory	(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.

requirements should apply, taking into account the intended purpose of the use of the system***, level of reliance of the user or business user on the output of the AI system for the final decision or outcome*** and according to the risk management system to be established by the provider.

Or. en

Amendment 615
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for ***users and affected persons***, certain mandatory requirements should apply, taking into account the intended purpose ***of the use*** of the system ***and according to*** the risk management system to be established by the provider.	(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for ***deployers and AI subjects***, certain mandatory requirements should apply, taking into account the intended purpose***, the potential or reasonably foreseeable use or misuse*** of the system***, and should be in accordance with*** the risk management system to be established by the provider.

Or. en

Amendment 616
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for users and affected persons, certain mandatory requirements should apply, taking into account the intended purpose ***of the*** use of	(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 ***or***

the system and according to the risk management system to be established by the provider.	***reasonably foreseeable*** use of the system and according to the risk management system to be established by the provider.

Or. en

Amendment 617
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 42

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

Or. en

Amendment 618
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and ***cybersecurity***. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as applicable in the light of the intended purpose of the system, and no other less	(43) Requirements should apply to high-risk AI systems as regards the quality ***and relevance*** of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and ***security***. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as ***well as the environment, society, rule of law,***

trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	***democracy, economic interests and consumer protection, as*** applicable in the light of the intended purpose***, the potential or reasonably foreseeable use or misuse*** of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 619
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety ***and*** fundamental rights, as applicable in the light of the intended purpose of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.	(43) Requirements should apply to high-risk AI systems as regards the quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety***,*** fundamental rights***, the environment and the Union values enshrined in Article 2 TEU***, as applicable in the light of the intended purpose ***or reasonably foreseeable use*** of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

Or. en

Amendment 620
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 43

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

Or. en

Amendment 621
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 43

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

Or. en

Amendment 622

Krzysztof Hetman, Andrzej Halicki, Adam Jarubas, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation
Recital 43 a (new)

Text proposed by the Commission	*Amendment*
	(43 a) Fundamental rights impact assessments for high-risk AI systems may include a clear outline of the intended purpose for which the system will be used, a clear outline of the intended geographic and temporal scope of the system's use, categories of natural persons and groups likely to be affected by the use of the system or any specific risk of harm likely to impact marginalised persons or groups at risk of discrimination, or increase societal inequalities;

Or. en

Amendment 623
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) High data quality ***is*** essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant***,*** representative ***and free of errors and complete*** in view of the intended purpose of the system. They should also have the appropriate statistical properties, including	(44) High data quality ***and having simple and accessible data plays a vital role in providing structure and ground truth for AI and are*** essential for ***purpose-ready data analytics and*** the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. ***To achieve simple access to and usability of high quality data for AI, the Commission should examine ways to facilitate the lawful processing of personal data to train legitimate AI systems by appropriate amendments to***

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

applicable laws. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, ***machine learning*** validation and testing data sets should be sufficiently relevant ***and*** representative in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, ***machine learning*** validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. ***If it is necessary for the aforementioned purpose to use existing sets of data that includes personal data originally collected and stored for a different purpose, their use for the aforementioned purpose should be deemed compatible with the original purpose so long as the personal data is not transferred to any third party.*** In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers ***should be*** able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems.

Or. en

Amendment 624
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 44

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

Or. fr

Amendment 625
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 44

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

Or. en

Amendment 626
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 44

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

Or. en

Amendment 627
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 44

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

Or. en

Amendment 628
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 44

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

Or. en

Amendment 629
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 44

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

Or. en

Amendment 630
Marion Walsmann

Proposal for a regulation
Recital 44

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

Or. en

Amendment 631
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44 a) Biases can be inherent in underlying datasets, especially when historical data is being used, introduced by the developers of the algorithms, or generated when the systems are implemented in real world settings. Any result provided by an AI system is necessarily influenced by the quality of the data used, and such inherent biases are inclined to gradually increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain ethnic groups or racialised communities.

Or. en

Amendment 632
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For	(45) For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission***, developed and operated by European actors and which do not transfer any data outside the territory or legal jurisdiction of the European Union,*** and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to

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

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

Or. fr

Amendment 633
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 45

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

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

Or. en

Amendment 634
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.	(46) Having information on how high-risk AI systems have been developed and how they perform throughout their lifecycle is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date. ***The required technical documentation may contain trade secrets in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. Possible trade secrets in the required***

documentation must be treated and kept in accordance with national legislation put in place in accordance with mentioned directive.

Or. en

Amendment 635
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 46

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

Or. en

Amendment 636
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) Having information on how high-risk AI systems have been developed and how they perform throughout their ***lifecycle*** is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.	(46) Having information on how high-risk AI systems have been developed and how they perform throughout their ***lifetime*** is essential to verify compliance with the requirements under this Regulation. This requires keeping records and the availability of a technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements***, while preserving trade secrets***. Such information should include the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used as well as documentation on the relevant risk management system. The technical documentation should be kept up to date.

Or. en

Amendment 637
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. ***Users*** should be able to interpret the ***system*** output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate.	(47) To address the opacity that may make certain AI systems incomprehensible to or too complex for natural persons, a certain degree of transparency should be required for high-risk AI systems. ***Deployers*** should be able to interpret the ***system's goals, priorities and*** output and use it appropriately. High-risk AI systems should therefore be accompanied by relevant documentation and instructions of use and include concise and clear information, including in relation to possible risks to fundamental rights and discrimination, where appropriate. ***Where individuals are passively subject to AI systems (AI subjects), information to***

ensure an appropriate type and degree of transparency should be made publicly available, with full respect to the privacy, personality, and related rights of subjects.

Or. en

Amendment 638
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei, Maria Grapini

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47 a) It is vital to ensure that the development, deployment and use of AI systems for the judiciary and law enforcement comply with fundamental rights, and are trusted by citizens, as well as in order to ensure that results generated by AI algorithms can be rendered intelligible to users and to those subject to these systems, and that there is transparency on the source data and how the system arrived at a certain conclusion. To this aim, law enforcement or judiciary authorities in the Union should use only such AI systems whose algorithms and logic are auditable and accessible at least to the police and the judiciary, as well as independent auditors, to allow for their evaluation, auditing and vetting, and such systems should not be closed or labelled as proprietary by the vendors.

Or. en

Amendment 639
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) High-risk AI systems should be designed and developed in such a way that natural persons ***can*** oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints ***that cannot be overridden by the system itself and is*** responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.	(48) High-risk AI systems should be designed and developed in such a way that natural persons ***may, when appropriate,*** oversee their functioning. For this purpose***, when it brings proven added value to the protection of health, safety and fundamental rights***, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints ***and are*** responsive to the human operator ***during the expected lifetime of the device where necessary to reduce risks as far as possible and achieve performance in consideration of the generally acknowledged state-of-the-art and technological and scientific progress***, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. ***By way of derogation regarding high-risk AI systems within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the Council, the established benefit-risk ratio requirements under the sectoral medical device legislation should apply.***

Or. en

Amendment 640
Deirdre Clune, Axel Voss, Andreas Schwab

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) High-risk AI systems should be designed and developed in such a way that natural persons ***can*** oversee their functioning. For this purpose, appropriate	(48) High-risk AI systems should be designed and developed in such a way that natural persons ***may, when appropriate,*** oversee their functioning. For this purpose***,***

human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints ***that cannot be overridden by the system itself and is*** responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

when it brings proven added value to the protection of health, safety and fundamental rights, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints ***and are*** responsive to the human operator ***during the expected lifetime of the device where necessary to reduce risks as far as possible and achieve performance in consideration of the generally acknowledged state-of-the-art technological and scientific progress***, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role. ***By way of derogation regarding high-risk AI systems within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the Council, the established benefit-risk ratio requirements under the sectoral medical device legislation should apply.***

Or. en

Amendment 641
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) High-risk AI systems should be designed and developed in such a way that natural persons ***can*** oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-	(48) High-risk AI systems should be designed and developed in such a way that natural persons ***may, when appropriate,*** oversee their functioning. For this purpose***, when it brings a proven added value to the protection of health, safety and fundamental rights***, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into

built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Or. en

Amendment 642
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself ***and*** is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.	(48) High-risk AI systems should be designed and developed in such a way that natural persons can ***actually*** oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself***, that it cannot make decisions without approval by the human operator, that it*** is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Or. fr

Justification

High-risk AI systems should not technically be capable of making a decision without instruction or supervision. The insertion of 'actually' ensures there is no room for

misinterpretation as to the key role natural persons have to play in the functioning of AI systems. Furthermore, human operators, who are subject to a duty of compliance when using high-risk AI systems, should be fully aware of actions taken by these systems and should not be able to allow the systems to self-supervise given the potential danger they present.

Amendment 643
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) High-risk AI systems should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be ***identified*** by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.	(48) High-risk AI systems should be designed and developed in such a way that natural persons can ***meaningfully*** oversee ***and regulate*** their functioning ***or investigate in case of an accident***. For this purpose, appropriate human oversight measures should be ***ensured*** by the provider of the system before its placing on the market or putting into service. In particular, where appropriate, such measures should guarantee that the system is subject to in-built operational constraints that cannot be overridden by the system itself and is responsive to the human operator, and that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Or. en

Amendment 644
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48 a) In order to protect natural persons

that are developers or users of AI systems against retaliation from their employers and colleagues, and to prevent misconduct or breaches of this Regulation and other relevant Union law, they should have the right to rely on the whistleblower protections set in Directive (EU) 2019/1937 of the European Parliament and of the Council.

Or. en

Amendment 645
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) High-risk AI systems should perform consistently throughout their ***lifecycle*** and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the users.	(49) High-risk AI systems should perform consistently throughout their ***lifetime*** and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the users. ***While standardisation organisations exist to establish standards, coordination on benchmarking is needed to establish how these standards should be met and measured. The European Artificial Intelligence Board should bring together national metrology and benchmarking authorities and provide guidance to address the technical aspects of how to measure the appropriate levels of accuracy and robustness. Their work should not be seen as a replacement of the standardisation organisations, but as a complementary function to provide specific technical expertise on measurement.***

Or. en

Amendment 646
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be communicated to the users.	(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art. The level of accuracy and accuracy metrics should be ***defined by standards or common technical specifications and*** communicated to the users. ***The European Commission should be able to decide on such standards or common technical specifications or to adopt existing ones developed by third parties such as suppliers, stakeholders or standardisation bodies.***

Or. fr

Amendment 647
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 49

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

Or. en

Amendment 648
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 50

Text proposed by the Commission	*Amendment*
(50) ***The*** technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors, faults, inconsistencies, unexpected situations) as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect ***the*** fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system.	(50) Technical robustness is a key requirement for high-risk AI systems. They should be resilient against risks connected to the limitations of the system (e.g. errors, faults, inconsistencies, unexpected situations) as well as ***adequately protected*** against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. Failure to protect against these risks could lead to safety impacts or negatively affect fundamental rights, for example due to erroneous decisions or wrong or biased outputs generated by the AI system.

Or. en

Amendment 649
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure.	(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure.

To ensure a level of cybersecurity appropriate to the risks, ***suitable*** measures should therefore be taken by the providers of high-risk AI systems***, also taking into account as*** appropriate ***the*** underlying ICT infrastructure.	To ensure a level of cybersecurity appropriate to the risks, ***state-of-the-art*** measures should therefore be taken ***into account*** by the providers of high-risk AI systems ***but also by the national competent authorities, market surveillance authorities and notified bodies that are accessing the data of providers of high-risk AI systems, next to*** appropriate underlying ICT infrastructure. ***It should be further taken into account that AI in the form of machine learning is a critical defence against malware representing a legitimate interest of the AI user.***

Or. en

Amendment 650
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation
Recital 51

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

infrastructure.

Or. en

Amendment 651
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 51

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

Or. en

Amendment 652
Karlo Ressler

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Cybersecurity plays a crucial role in	(51) Cybersecurity plays a crucial role in

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

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

Or. en

Amendment 653
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can ***leverage*** AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures	(51) Cybersecurity plays a crucial role in ensuring that AI systems are resilient against attempts to alter their use, behaviour, performance or compromise their security properties by malicious third parties exploiting the system's vulnerabilities. Cyberattacks against AI systems can ***target*** AI specific assets, such as training data sets (e.g. data poisoning) or trained models (e.g. adversarial attacks), or exploit vulnerabilities in the AI system's digital assets or the underlying ICT infrastructure. To ensure a level of cybersecurity appropriate to the risks, suitable measures should therefore be taken

should therefore be taken by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.	by the providers of high-risk AI systems, also taking into account as appropriate the underlying ICT infrastructure.

Or. en

Amendment 654
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 51

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

Or. fr

Amendment 655
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market or putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.	(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market or putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system***, without prejudice to the right of a provider to take action against the manufacturer of that system***.

Or. fr

Amendment 656
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market ***or*** putting into service of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.	(53) It is appropriate that a specific natural or legal person, defined as the provider, takes the responsibility for the placing on the market***,*** putting into service ***or deploying*** of a high-risk AI system, regardless of whether that natural or legal person is the person who designed or developed the system.

Or. en

Amendment 657
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) The provider should establish a sound quality management system, ensure	(54) The provider ***and, where applicable, deployer*** should establish a

the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.	sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question. ***Deployers should have strategies in place to ensure that the data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data during the deployment lifetime of high-risk AI systems, complies with applicable rules and ensure regulatory compliance, in particular regarding modifications to the high-risk AI systems.***

Or. en

Amendment 658
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Recital 54

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

quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 659
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.	(54) ***Unless the provider has already implemented a risk management system warranting quality and conformity,*** the provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 660
Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Recital 54

Text proposed by the Commission	*Amendment*
(54) The provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.	(54) ***In case there are no risk management systems already in place,*** the provider should establish a sound quality management system, ensure the accomplishment of the required conformity assessment procedure, draw up the relevant documentation and establish a robust post-market monitoring system. Public authorities which put into service high-risk AI systems for their own use may adopt and implement the rules for the quality management system as part of the quality management system adopted at a national or regional level, as appropriate, taking into account the specificities of the sector and the competences and organisation of the public authority in question.

Or. en

Amendment 661
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to ***making their AI systems available in*** the Union, where an importer cannot be identified, ***providers*** established outside the Union ***shall***, by written mandate, appoint ***an authorised*** representative established in the Union.	(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to ***placing any AI system on*** the Union ***market, putting it into service or using it***, where an importer cannot be identified, ***operators*** established outside the Union ***should***, by written mandate, appoint ***a legal*** representative

established in the Union. ***The legal representative should act on behalf of the operator and may be addressed by any competent authorities for the purpose of this Regulation. The designation of such a legal representative does not affect the responsibility or liability of the operator under this Regulation. Such a legal representative should perform its tasks according to the mandate received from the operator, including cooperating with the national supervisory authorities with regard to any action taken to ensure compliance with this Regulation. The designated legal representative should be subject to enforcement proceedings in the event of non-compliance by the operator.***

Or. en

Amendment 662
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to making their AI systems available in the Union, ***where an importer cannot be identified,*** providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.	(56) To enable enforcement of this Regulation and create a level-playing field for operators, and taking into account the different forms of making available of digital products, it is important to ensure that, under all circumstances, a person established in the Union can provide authorities with all the necessary information on the compliance of an AI system. Therefore, prior to making their AI systems available in the Union, providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.

Or. en

Amendment 663
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Róża Thun und Hohenstein, Alin Mituța

Proposal for a regulation
Recital 58

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

Or. en

Amendment 664
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) Given the nature of AI systems and	(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.	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 ***for the purpose for which they were intended and*** in accordance with the instructions of use***, to that end high-risk AI systems should structurally limit, to the greatest extent possible, the technical possibility for a user to use these AI systems in another way,*** and certain other obligations should be provided for with regard to monitoring of the functioning of the AI systems and with regard to record-keeping, as appropriate.

Or. fr

Amendment 665
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 58

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

Or. en

Amendment 666
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) Whilst risks related to AI systems can generate from the way such systems are designed, risks can as well stem from how such AI systems are used. Users of high-risk AI system therefore play a critical role in ensuring that fundamental rights are protected, complementing the obligations of the provider when developing the AI system. Users are best placed to understand how the high-risk AI system will be used concretely and can therefore identify potential risks that were not foreseen in the development phase, thanks to a more precise knowledge of the context of use, the people or groups of people likely to be affected, including marginalised and vulnerable groups. In order to efficiently ensure that fundamental rights are protected, the user of high-risk AI systems should therefore carry out a fundamental rights impact assessment on how it intends to use such AI systems, and prior to putting it into use. The impact assessment should be accompanied by a detailed plan describing the measures or tools that will help mitigating the risks to fundamental rights identified. When performing this impact assessment, the user should notify the national supervisory authority, the market surveillance authority as well as relevant stakeholders. It should also involve representatives of groups of persons likely to be affected by the AI system in order to collect relevant information which is deemed necessary to perform the impact assessment.

Or. en

Amendment 667
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) To ensure that fundamental rights, the environment and the public interest are effectively protected where an AI-system is classified as high-risk under Annex III, both producers and deployers before each deployment should perform a fundamental rights impact assessment of the systems' impact in the context of use throughout the entire lifecycle and include measures to mitigate any impact on fundamental rights, the environment or the public interest. The fundamental rights impact assessment should be registered in the public EU database for stand-alone high-risk AI systems and be publicly accessible. The supervisory authority should have the power to review these fundamental rights impact assessments.

Or. en

Amendment 668
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) Risks for people affected by AI systems often arise from uses of an AI system in a specific context and with respect to a specific group of people, and

might not always be foreseeable for the provider. Therefore, prior to putting a high-risk AI system into use, the user should conduct an assessment of the system's impact on the fundamental rights in particular, within the context of use, and publish the results.

Or. en

Amendment 669
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(59) It is appropriate to envisage that the user of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated ***except where the use is made in the course of a personal non-professional activity***.	(59) It is appropriate to envisage that the user of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated.

Or. fr

Amendment 670
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(59) It is appropriate to envisage that the ***user*** of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity.	(59) It is appropriate to envisage that the ***deployer*** of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity.

Or. en

Amendment 671
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.	(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation and with competent authorities established under this Regulation. ***This provision shall qualify as a legal obligation in the context of the processing of personal data where necessary for the cooperation between the relevant providers.***

Or. en

Amendment 672
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and ***users*** to enable their	(60) In the light of the complexity of the artificial intelligence value chain, relevant third parties, notably the ones involved in the sale and the supply of software, software tools and components, pre-trained models and data, or providers of network services, should cooperate, as appropriate, with providers and ***deployers*** to enable

compliance with the obligations under this Regulation and with competent authorities established under this Regulation.

their compliance with the obligations under this Regulation and with competent authorities established under this Regulation.

Or. en

Amendment 673
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards ***as defined*** in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54]should ***be a means for providers*** to demonstrate ***conformity*** with the requirements of this Regulation***. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient***.	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation***, in particular as regards the levels and metrics of accuracy and robustness for high-risk AI systems. The Commission should be able to adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient. The Commission should also be able to adopt standards or common technical specifications developed by third parties such as suppliers, stakeholders or standardisation bodies***. Compliance with ***the common technical specifications adopted by the Commission should be a means for suppliers to demonstrate compliance with the requirements of this Regulation. Compliance with other*** harmonised standards ***set out*** in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should ***also help*** to demonstrate ***suppliers' compliance*** with the requirements of this Regulation***, without having the same probative value as the common technical specifications adopted by the Commission***.
[54] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of	[54] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of

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

Or. fr

Amendment 674
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient.	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission could adopt common technical specifications in areas where no harmonised standards exist ***and are not expected to be published within a reasonable period*** or where they are insufficient***, only after consulting the Artificial Intelligence Board, the European standardisation organisations as well as the relevant stakeholders. The Commission should duly justify why it decided not to use harmonised standards.***
[54] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of	[54] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of

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

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

Or. en

Amendment 675
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, the Commission ***could*** adopt common technical specifications in areas where no harmonised standards exist or where they are insufficient.	(61) Standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation. Compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[54] should be a means for providers to demonstrate conformity with the requirements of this Regulation. However, ***in exceptional cases, where industry and technical experts consider that pressing and specific safety or fundamental rights concerns cannot be addressed by established standardisation processes,*** the Commission ***may*** adopt common technical specifications in areas where no harmonised standards exist or where they are ***evidently*** insufficient.
[54] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and	[54] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and

Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Or. en

Amendment 676
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 61 a (new)

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

Or. en

Amendment 677
Jörgen Warborn, Tomas Tobé, Arba Kokalari

Proposal for a regulation
Recital 61 a (new)

Text proposed by the Commission	*Amendment*
	(61 a) Striving for regulatory alignment on AI with likeminded global partners is key to fostering mutual innovation and cross-border partnerships within the field of AI. Coordination with international standardisation bodies is therefore of great importance.

Or. en

Amendment 678
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.	(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service. ***AI systems, including general purpose AI systems, that may not necessarily be high-risk, are frequently used as components of other AI or non-AI software systems. In order to increase trust in the value chain and to give certainty to businesses about the performance of their systems, providers may voluntarily apply for a third-party conformity assessment.***

Or. en

Amendment 679
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service.	(62) In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a ***third party*** conformity assessment prior to their placing on the market or putting into service.

Or. en

Amendment 680
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is appropriate that, in order to minimise the burden on operators and avoid any possible duplication, for high-risk AI systems related to products which are covered by existing Union harmonisation legislation following the New Legislative Framework approach, the compliance of those AI systems with the requirements of this Regulation should be assessed as part of the conformity assessment already foreseen under that legislation. The applicability of the requirements of this Regulation should thus not affect the specific logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. This approach is fully reflected in the interplay between this Regulation and the [Machinery Regulation]. While safety risks of AI systems ensuring safety functions in machinery are addressed by the requirements of this Regulation, certain specific requirements in the [Machinery Regulation] will ensure the safe integration of the AI system into the overall machinery, so as not to compromise the safety of the machinery as a whole. The	(63) It is appropriate that, in order to minimise the burden on operators and avoid any possible duplication, for high-risk AI systems related to products which are covered by existing Union harmonisation legislation following the New Legislative Framework approach, the compliance of those AI systems with the requirements of this Regulation should be assessed as part of the conformity assessment already foreseen under that legislation. The applicability of the requirements of this Regulation should thus not affect the specific logic, methodology or general structure of conformity assessment under the relevant specific New Legislative Framework legislation. This approach is fully reflected in the interplay between this Regulation and the [Machinery Regulation]. While safety risks of AI systems ensuring safety functions in machinery are addressed by the requirements of this Regulation, certain specific requirements in the [Machinery Regulation] will ensure the safe integration of the AI system into the overall machinery, so as not to compromise the safety of the machinery as a whole. The

[Machinery Regulation] applies the same definition of AI system as this Regulation.	[Machinery Regulation] applies the same definition of AI system as this Regulation. ***However, should this Regulation and another legislative act of the European Union both cover the same product or component of a product and provide diverging definitions or impose different safety requirements, the applicable text shall be the one with the definition or safety requirements offering the best protection for people, Member States, society and fundamental rights.***

Or. fr

Amendment 681
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 64

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

Or. en

Amendment 682
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 64

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

Or. fr

Amendment 683
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Vlad-Marius Botoş, Samira Rafaela, Monica Semedo, Salima Yenbou, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is	(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is

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

appropriate to limit, at least in an initial phase of application of this Regulation, the scope of application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility, with the exception of AI systems intended to be used for the remote biometric identification of persons ***and AI systems intended to be used to make inferences on the basis of biometric data that produce legal effects or affect the rights and freedoms of natural persons. For those types of AI systems*** the involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited**.**

Or. en

Amendment 684
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is ***appropriate to limit, at least in an initial phase of*** application of this Regulation, the ***scope of*** application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility***, with the only exception of AI systems intended to be used for the remote biometric identification of persons, for which the***	(64) Given the more extensive experience of professional pre-market certifiers in the field of product safety and the different nature of risks involved, it is ***essential to ensure, particularly in the period before*** application of this Regulation, the ***development of adequate capacity for the*** application of third-party conformity assessment for high-risk AI systems other than those related to products. Therefore, the conformity assessment of such systems should be carried out as a general rule by the provider under its own responsibility.

involvement of a notified body in the conformity assessment should be foreseen, to the extent they are not prohibited.

Or. en

Amendment 685
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 64

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

Or. en

Justification

Instead of blanketly banning the law enforcement's use of facial recognition AI, these systems should be incorporated in the list of high-risk AI systems and subject to strict control. Such modern AI software can process information and images at lightning speed and with great precision - tasks that would take days for a human law enforcement agent to go through. Also with much less risk of bias, when the programs are diligently designed. Using such technology can help law enforcement not only prevent crimes, but also react rapidly when they occur, and provide a very powerful tool to investigate serious crimes.

Amendment 686
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. en

Amendment 687
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(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.	(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***,*** absence of conflicts of interests ***and minimum cybersecurity requirements***.

Or. en

Amendment 688
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona

Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Alin Mituța

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(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.	(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

Amendment 689
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(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.	(65) In order to carry out third-party conformity assessment for AI systems intended to be used for ***any of the use-cases listed in Annex III***, 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

Amendment 690
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä

on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 65 a (new)

Text proposed by the Commission	*Amendment*
	(65 a) Third party conformity assessments for products listed in Annex III are essential as a precautionary measure and to ensure that trust is not lost in AI products, to the detriment of innovation, competition and growth. Due to the particularly sensitive nature of the tasks at hand, third party conformity assessments in the fields of law enforcement, asylum and immigration should be carried out by the market surveillance authority.

Or. en

Amendment 691
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been ***pre-determined*** by the provider and assessed at	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may ***create a new or increased risk and significantly*** affect the compliance of the system with this Regulation or when the intended purpose of the system changes***. If such a case materialises, the provider should follow a clear procedure with fixed deadlines, transparency requirements and reporting duties involving, where appropriate and applicable, external oversight by notified bodies or, where it is covered already under the relevant sectoral legislation,***

the moment of the conformity assessment should not constitute a substantial modification.	***post market monitoring if that is needed***. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been ***considered*** by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification. ***In addition, it should not be considered a substantial modification if the user trains an AI system. In this situation, the user should clearly delimit the effects that the learning can have for the AI system. The notion of substantial modification should be assessed in light of the essential requirements set in this Regulation and be left to the manufacturer to determine if a modification is deemed to be substantial.***

Or. en

Amendment 692
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is

necessary ***to provide rules establishing*** that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment ***should not constitute a substantial modification***.	necessary that changes to the algorithm and its performance that ***constitute substantial modifications are subject to new conformity assessments, including in cases where the substantial modifications*** have been pre-determined by the provider and assessed at the moment of the ***initial*** conformity assessment.

Or. fr

Amendment 693
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose ***or reasonably foreseeable use*** of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Or. en

Amendment 694
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.	(66) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new ***third party*** conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification.

Or. en

Amendment 695
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 66

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

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

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

Or. en

Amendment 696
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 66 a (new)

Text proposed by the Commission	*Amendment*
	(66 a) To prevent any deterioration in the expected safety of the algorithm subject to significant changes independent of the providers control, a clearly developed plan to address such significant changes should be subject to oversight by the relevant competent authorities or notified bodies when it is already addressed in principle in the respective sectoral Union harmonisation legislation regarding post-market monitoring

Or. en

Amendment 697
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal	(67) High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal

market. Member States should not create ***unjustified*** obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.	market. Member States should not create obstacles to the placing on the market or putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking.

Or. en

Amendment 698
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş 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

Amendment 699
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

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	***deleted***

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.

Or. en

Amendment 700
Vincenzo Sofo, Kosma Złotowski

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

Amendment 701
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 68

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

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.

Or. en

Amendment 702
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers ***and users*** of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system ***or the use thereof*** in a EU database, to be established and managed by the Commission***. Certain AI systems listed in Article 52 (1b) and (2) and uses thereof shall be registered in the EU database. In order to facilitate this, users shall request information listed in Annex VIII point 2(g) from providers of AI systems. Any uses of AI systems by public authorities or on their behalf shall also be registered in the EU database. In order to facilitate this, public authorities shall request information listed in Annex VIII point 3(g) from providers of AI systems***. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council. In

order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. ***In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the European Accessibility Act.***

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

Or. en

Amendment 703
Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers ***and users*** of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system ***or the use thereof*** in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] .

the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report. ***In order to maximise the availability and use of the database by the public, the database, including the information made available through it, should comply with requirements under the European Accessibility Act.***

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

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

Or. en

Amendment 704
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] .	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, ***both*** providers ***and users*** of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission***. Users who are public authorities or European Union institutions, bodies, offices and agencies or users acting on their behalf should also***

In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.	***register in the EU database before putting into service or using any AI system***. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.
[55] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).	[55] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 705
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers of high-risk AI systems ***other than those related to products falling within the scope of relevant existing Union harmonisation legislation,*** should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU)	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards the public, providers ***and deployers*** of high-risk AI systems should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when

2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

deployed, the procedure for setting the database should include the elaboration of functional specifications by the Commission and an independent audit report.

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

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

Or. en

Amendment 706
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards ***the public***, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of functional specifications by	(69) In order to facilitate the work of the Commission and the Member States in the artificial intelligence field as well as to increase the transparency towards ***regulators***, providers of high-risk AI systems other than those related to products falling within the scope of relevant existing Union harmonisation legislation, should be required to register their high-risk AI system in a EU database, to be established and managed by the Commission. The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[55] . In order to ensure the full functionality of the database, when deployed, the procedure for setting the database should include the elaboration of

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

Or. en

Amendment 707
Geoffroy Didier

Proposal for a regulation
Recital 70

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

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

places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. ***Besides, recommendation systems, in particular automated decision-making algorithms that disseminate and order cultural and creative content displayed to users, should be designed in such a way that their personalised suggestions are explainable and non-discriminatory. A clear explanation of the parameters used for the personalised suggestions should be easily accessible and understandable to the users. Natural persons should have a right to opt out of recommended and personalised services without affecting their right to use the core service.***

Or. en

Justification

In line with the changes made in Article 52 (3) and (3bis)

Amendment 708
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 70

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

circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.	circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. ***Images generated through the use of AI in the creation of audio-visual content such as films and video game visuals should not be considered "deep fakes" as defined in Article 52 (3), which must be consistent with the principle of artistic freedom under the Charter of Fundamental Rights.***
	Or. en

Amendment 709
Morten Løkkegaard

Proposal for a regulation
Recital 70

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

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

system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. ***Images generated through the use of AI in the creation of audiovisual content such as films and video game visuals should not be considered "deep fakes" as defined in Article 52 (3), which must be consistent with the principle of artistic freedom under the Charter of Fundamental Rights.***

Or. en

Amendment 710
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 70

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

notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.	notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use ***or where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video game visuals or analogous work***. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose ***in an appropriate, clear and visible manner*** that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 711
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 70

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

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

system, unless this is obvious from the circumstances and the context of use. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, ***deployers***, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin. ***Additionally, the use of an AI system to generate or manipulate image, audio or video content that appreciably resembles a natural person should be permitted only when used for freedom of expression and artistic purposes and while respecting the limits of these purposes, or with the explicit consent of that person.***

Or. en

Amendment 712
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Recital 70

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

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

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

Or. en

Amendment 713
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Recital 70

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

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

Or. en

Amendment 714
Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 70

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

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

to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Or. en

Amendment 715
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*
(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system***, unless this is obvious from the circumstances and the context of use***. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, ***users, who use an AI system*** to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should ***disclose*** that the content has been artificially created or	(70) Certain AI systems intended to interact with natural persons or to generate content may pose specific risks of impersonation or deception irrespective of whether they qualify as high-risk or not. In certain circumstances, the use of these systems should therefore be subject to specific transparency obligations without prejudice to the requirements and obligations for high-risk AI systems. In particular, natural persons should be notified that they are interacting with an AI system. Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Further, ***AI systems used*** to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should ***systematically contain an indication on the content generated*** that the content has been artificially created or manipulated***, and users who use such AI***

manipulated ***by labelling the artificial intelligence output accordingly and disclosing its artificial origin***.	***systems or reuse the content generated should not be allowed to remove or conceal that indication***.

Or. fr

Amendment 716
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70 a) In light of the nature and complexity of the value chain for AI systems, it is essential to clarify the role of humans who may contribute to the development of AI systems covered by this Regulation, without being providers, no longer being providers or when other natural or legal persons have also become providers. Therefore, it is particularly important to clarify the legal situation when it comes to general purpose AI systems. Those AI system are able to perform generally applicable functions such as image/speech recognition, audio/video generation, pattern detection, question answering or translation in a plurality of contexts. Every natural or legal person can become a new provider by adapting a general purpose AI system, already placed on the market or put into service, to a specific intended purpose. Due to their peculiar nature and in order to ensure a fair sharing of responsibilities along the AI value chain, such general purpose AI system should however already be subject to proportionate and tailored requirements and obligations under this Regulation even before placing it on the Union market or putting it into service. The original provider of a general purpose AI system should furthermore cooperate, as appropriate, with the new provider to enable its compliance with the relevant obligations under this

Regulation.

Or. en

Amendment 717
Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation
Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70 a) Suppliers of general purpose AI systems and, as relevant, other third parties that may supply other software tools and components, including pre-trained models and data, should cooperate, as appropriate, with providers that use such systems or components for an intended purpose under this Regulation in order to enable their compliance with applicable obligations under this Regulation and their cooperation, as appropriate, with the competent authorities established under this Regulation. In such cases, the provider may, by written agreement, specify the information or other assistance that such supplier will furnish in order to enable the provider to comply with its obligations herein.

Or. en

Amendment 718
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe ***and fully controlled***

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

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

Or. en

Amendment 719
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Artificial intelligence is a rapidly developing family of technologies that requires ***novel forms of*** regulatory oversight ***and*** a safe space for experimentation, ***while*** ensuring	(71) Artificial intelligence is a rapidly developing family of technologies that ***benefits from clear rules and legal certainty, and*** requires regulatory oversight***. In order to fulfill its potential to***

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

benefit society, a safe space for ***controlled*** experimentation, ensuring ***respect for Union law and the protection of fundamental rights, can help foster*** responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that ***promotes sustainable innovation,*** is future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to ***cooperate in establishing*** artificial intelligence regulatory sandboxes to facilitate the development and testing of AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

Or. en

Amendment 720
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş 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	*Amendment*
(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, ***national competent authorities from one or more*** Member States should ***be encouraged to*** establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put	(71) Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory 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

Amendment 721
Karlo Ressler

Proposal for a regulation
Recital 71

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

Or. en

Amendment 722
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Artificial intelligence is a rapidly developing family of technologies that	(71) Artificial intelligence is a rapidly developing family of technologies that

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

Or. en

Amendment 723
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 71

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

Or. en

Amendment 724
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. ***This Regulation should provide the legal basis for the use of*** personal data collected for ***other*** purposes ***for developing certain AI systems in the public interest*** within the ***AI regulatory sandbox, in line with Article 6(4)*** of Regulation (EU) 2016/679***, and*** Article ***6 of*** Regulation ***(EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680***. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any ***high-risks*** to safety and fundamental rights that may arise during the	(72) The objectives of the regulatory sandboxes should be to foster AI innovation ***for the benefit of society*** by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring ***respect for and protection of fundamental rights,*** compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. Personal data ***that had originally been*** collected for ***different*** purposes ***should be processed in a sandbox only under specified conditions and*** within the ***limits*** of Regulation (EU) 2016/679***. Such further processing should be considered as for statistical purposes in the meaning of*** Article ***5(1)(b) of that*** Regulation. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any ***risks*** to safety and

development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide ***over the suspending or banning them from participating in the sandbox, or*** whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680. ***This Regulation should also provide the legal basis for the use of data protected by intellectual property or trade-secrets for developing certain AI systems in the public interest within the AI regulatory sandbox, without prejudice to Directive (EU) 2019/790 and to Directive (EU) 2016/943. The authorised use of data protected by intellectual property or trade-secrets under Article 54 of this Regulation should be covered by Article 4 of Directive (EU) 2019/790.***

Or. en

Amendment 725
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, ***and*** to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs)	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a ***strictly*** controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation***, as well as with the Charter of Fundamental Rights of the European Union and the General Data Protection Regulation***; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities,

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

emerging risks and the impacts of AI use, ***to provide safeguards needed to build trust and reliance on AI systems,*** to accelerate access to markets, including by removing barriers for ***the public sector,*** small and medium enterprises (SMEs) and start-ups***; and to contribute to the development of ethical, socially responsible and environmentally sustainable AI systems***. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Or. en

Amendment 726
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. ***This Regulation should provide the legal basis for the use of personal data collected for other purposes for developing certain AI systems in the public interest within the AI regulatory sandbox, in line with Article 6(4) of Regulation (EU) 2016/679, and Article 6 of Regulation (EU) 2018/1725, and without prejudice to Article 4(2) of Directive (EU) 2016/680.*** Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and	(72) The objectives of the regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and Member States legislation; to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups. To ensure uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation and a framework for cooperation between the relevant authorities involved in the supervision of the sandboxes. Participants in the sandbox should ensure appropriate safeguards and cooperate with the competent authorities, including by following their guidance and acting expeditiously and in good faith to mitigate any high-risks to safety and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the participants in the sandbox should be taken into account when competent authorities decide whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

Article 57 of Directive 2016/680.

Or. en

Justification

Consistent with the deletion of Article 54.

Amendment 727
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar

Proposal for a regulation
Recital 72

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

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

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

Or. en

Amendment 728
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 72 a (new)

Text proposed by the Commission	*Amendment*
	(72 a) To ensure that Artificial Intelligence leads to socially and environmentally beneficial outcomes, Member States should support and promote research and development of AI in support of socially and environmentally beneficial outcomes by allocating sufficient resources, including public and Union funding, and giving priority access to regulatory sandboxes to projects led by civil society. Such projects should be based on the principle of interdisciplinary cooperation between AI developers, experts on inequality and non-discrimination, accessibility, consumer, environmental, and digital rights, as well as academics.

Or. en

Amendment 729
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) In order to promote and protect innovation, it is important that the interests of ***small-scale*** providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of ***small-scale*** providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.	(73) In order to promote and protect innovation, it is important that the interests of ***SME*** providers and users of AI systems are taken into particular account. To this objective***, AI solutions and services designed to combat fraud and protect consumers against fraudulent activities should not be considered high-risk, nor be prohibited. As a matter of substantial public interest, it is vital that this Regulation does not undermine the incentive of industry to create and roll out solutions designed to combat fraud across the Union. Furthermore***, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of ***SME*** providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users. ***Member States should also be encouraged to do the same for small and medium enterprises, which may sometimes lack the requisite administrative and legal resources to ensure proper understanding and compliance with the provisions under this act. In the event that Member States***

request it, the Commission may also provide assistance in this regard.

Or. en

Amendment 730
Marion Walsmann

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) In order to promote and protect innovation, it is important that the interests of small-scale providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should ***possibly*** ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.	(73) In order to promote and protect innovation, it is important that the interests of small-scale providers***, like SMEs, micro-enterprises*** and users of AI systems are taken into particular account***. SMEs are the backbone of the European economy and they face more challenges adapting to new legislations therefore measures should be foreseen to support them to cope with the new obligations or to exclude them from certain requirements***. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of small-scale providers shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers and other operators, notably those of a smaller scale. Member States should ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.

Or. en

Amendment 731
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 73

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

Or. fr

Amendment 732
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) In order to promote and protect innovation, it is important that the interests of small-scale providers and ***users*** of AI systems are taken into particular account.	(73) In order to promote and protect innovation, it is important that the interests of small-scale providers and ***deployers*** of AI systems are taken into particular

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

Or. en

Amendment 733
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Dita Charanzová, Andrus Ansip, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Catharina Rinzema, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) In order to promote and protect innovation, it is important that the interests of ***small-scale*** providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of ***small-scale providers*** shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost for providers	(73) In order to promote and protect innovation, it is important that the interests of ***start-ups and SME*** providers and users of AI systems are taken into particular account. To this objective, Member States should develop initiatives, which are targeted at those operators, including on awareness raising and information communication. Moreover, the specific interests and needs of ***SMEs and start-ups*** shall be taken into account when Notified Bodies set conformity assessment fees. Translation costs related to mandatory documentation and communication with authorities may constitute a significant cost

and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.	for providers and other operators, notably those of a smaller scale. Member States should possibly ensure that one of the languages determined and accepted by them for relevant providers' documentation and for communication with operators is one which is broadly understood by the largest possible number of cross-border users.

Or. en

Amendment 734
Kosma Złotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation
Recital 73 a (new)

Text proposed by the Commission	*Amendment*
	(73 a) AI solutions and services designed to combat fraud and protect consumers against fraudulent activities should not be considered high risk, nor prohibited. As a matter of substantial public interest, it is vital that this Regulation does not undermine the incentive of the industry to create and roll out solutions designed to combat fraud across the European Union.

Or. en

Amendment 735
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 74

Text proposed by the Commission	*Amendment*
(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, the AI-	(74) In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market as well as to facilitate compliance of providers and notified bodies with their obligations under this Regulation, ***Member***

on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level ***should possibly contribute to the implementation of this Regulation***. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.	***States should utilise existing dedicated channels for communication with SMEs and start-ups. Such existing channels could include but are not limited to ENISA's Computer Security Incident Response Teams, National data protection agencies,*** the AI-on demand platform, the European Digital Innovation Hubs and the Testing and Experimentation Facilities established by the Commission and the Member States at national or EU level. Within their respective mission and fields of competence, they may provide in particular technical and scientific support to providers and notified bodies.

Or. en

Amendment 736
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 74

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

Or. en

Amendment 737
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 74

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

Or. en

Amendment 738
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) In order to facilitate a smooth, effective and ***harmonised*** implementation of this Regulation ***a*** European Artificial Intelligence Board should be established. The Board should be responsible for a number of ***advisory*** tasks, including issuing opinions, recommendations, advice or guidance on matters related to the	(76) In order to facilitate a smooth, effective and ***consistent*** implementation of this Regulation ***an independent*** European Artificial Intelligence Board should be established. The Board should be responsible for a number of tasks, including issuing opinions, recommendations, advice or guidance on

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.	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***, including on possible amendments of the annexes, in particular the annex listing high-risk AI systems***. ***To contribute to the effective and harmonised enforcement of this Regulation, the Board should also be able to adopt binding decisions for the settlement of cases involving two or more Member States in which the national supervisory authorities are in disagreement or when it is not clear who the lead national supervisory authority is. The Board should also be able to adopt a binding decision in those cases when a national supervisory authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the compliance with obligations under Union or national law intended to protect fundamental rights, the principles of Article 4a, the values as enshrined in Article 2 TEU, the environment, or to other aspects of public interest protection.***

Or. en

Amendment 739
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Karen Melchior, Alin Mituța

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) In order to ***facilitate a smooth,*** effective and harmonised implementation of this Regulation ***a European*** Artificial Intelligence ***Board*** should be established. The Board should be responsible for ***a***	(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***

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.***

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

Amendment 740
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or	(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 ***independent and*** responsible for a number of advisory ***and enforcement*** tasks, including issuing

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.

decisions, 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. ***In order to ensure a consistent and appropriate enforcement vis-à-vis very large undertakings, the Board should be the supervisory authority for undertakings that meet the criteria of 'community dimension' as defined in Article 1(3) of Regulation 139/200 (Merger Regulation). The Board should have a secretariat with sufficient resources and expertise to be able to fulfil its role. In this respect, the secretariat should establish a European Centre of Excellence for Artificial Intelligence (ECE-AI).***

Or. en

Amendment 741
Svenja Hahn, Dragoş Tudorache, Nicola Beer, Karen Melchior, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Sophia in 't Veld, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the	(76) In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established ***as a body of the Union and should have legal personality***. 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

Commission on specific questions related to artificial intelligence.	this Regulation and providing advice to and assisting the Commission ***and the national competent authorities*** on specific questions related to artificial intelligence.

Or. en

Amendment 742
Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Radosław Sikorski, Janusz Lewandowski

Proposal for a regulation
Recital 76 a (new)

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

Or. en

Amendment 743
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 76 a (new)

Text proposed by the Commission	*Amendment*
	(76 a) The Commission should re-

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

Or. en

Amendment 744
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority.	(77) Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority. ***In order to avoid duplication and combine expertise and competences, this should be a supervisory authority established under Regulation (EU) 2016/679 (General Data Protection Regulation). The supervisory authorities should have sufficient investigative and corrective powers.***

Or. en

Amendment 745
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) ***Member States hold a key role in the application and enforcement of this Regulation. In this respect,*** each Member State should designate ***one or more*** national competent authorities ***for the purpose of supervising the application and*** implementation of this Regulation. ***In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at*** Member State ***and Union levels, in each Member State one national authority should be designated as*** national supervisory authority.	(77) Each Member State should ***establish or*** designate ***a single national supervisory authority to act as the lead authority and be responsible for ensuring the effective coordination between the*** national competent authorities ***regarding the*** implementation of this Regulation. ***It should also represent its*** Member State ***on the Board. Each*** national supervisory authority ***should act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation***.

Or. en

Amendment 746
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission	*Amendment*
	(77 a) The national supervisory authorities should monitor the application of the provisions pursuant to this Regulation and contribute to its consistent application throughout the Union. For that purpose, the national supervisory authorities should cooperate with each other, with the market surveillance authorities and with the Commission, without the need for any agreement

between Member States on the provision of mutual assistance or on such cooperation.

Or. en

Amendment 747
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 78

Text proposed by the Commission	*Amendment*
(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.	(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. ***In view of the sensitive nature of high-risk AI systems, this post-market monitoring system should not be able to automatically send data or error reports to the supplier via the AI system.*** This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to have a system in place to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

Or. fr

Amendment 748
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 78

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

Or. en

Amendment 749
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 78

Text proposed by the Commission	*Amendment*
(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being	(78) In order to ensure that providers of high-risk AI systems can take into account the experience on the use of high-risk AI systems for improving their systems and the design and development process or can take any possible corrective action in a timely manner, all providers should have a post-market monitoring system in place. This system is also key to ensure that the possible risks emerging from AI systems which continue to 'learn' after being

placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to ***have a system in place to*** report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

placed on the market or put into service can be more efficiently and timely addressed. In this context, providers should also be required to report to the relevant authorities any serious incidents or any breaches to national and Union law protecting fundamental rights resulting from the use of their AI systems.

Or. en

Amendment 750
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 79

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

Or. en

Amendment 751
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 79 a (new)

Text proposed by the Commission	*Amendment*
	(79 a) As the rights and freedoms of individuals can be seriously undermined by AI systems, it is essential that affected individuals have meaningful access to reporting and redress mechanisms. They should be able to report infringements of this Regulation to their national supervisory authority and have the right to be heard and to be informed about the outcome of their complaint and the right to a timely decision. In addition, they should have the right to an effective remedy against competent authorities who fail to enforce these rights and the right to redress. Where applicable, deployers should provide internal complaints mechanisms to be used by affected individuals and should be liable for pecuniary and non-pecuniary damages in cases of breaches of individuals' or groups' rights. Collective representation of affected individuals must be possible.

Or. en

Amendment 752
Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of	(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of

those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and

those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. ***With regard to use case 5(b) in Annex III, areas covered by this Regulation relate to those outlined in Article 1(a). All other procedures relating to creditworthiness assessment are covered by the Directive of the European Parliament and of the Council on consumer credits .***

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and

repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 753
Andrea Caroppo, Salvatore De Meo

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality	(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality

management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU. ***With regard to use case 5(b) in Annex III, areas covered by this Regulation relate to those outlined in Article 1(a). All other procedures relating to creditworthiness assessment are covered by the Directive of the European Parliament and of the Council on consumer credits.***

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 754
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the	(80) Union legislation on financial services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the

European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. ***In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.***

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

European Central Bank, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, including for market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU.

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 755
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) Union legislation on financial	(80) Union legislation on financial

services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the European ***Central Bank***, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, ***including for*** market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56] , it is also appropriate to integrate the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and

services includes internal governance and risk management rules and requirements which are applicable to regulated financial institutions in the course of provision of those services, including when they make use of AI systems. In order to ensure coherent application and enforcement of the obligations under this Regulation and relevant rules and requirements of the Union financial services legislation, the ***competent*** authorities responsible for the supervision and enforcement of the financial services legislation, including where applicable the ***competent authorities as defined in Directive 2013/36/EU of the*** European ***Parliament and of the Council***, should be designated as competent authorities for the purpose of supervising the implementation of this Regulation, ***excluding*** market surveillance activities, as regards AI systems provided or used by regulated and supervised financial institutions. To further enhance the consistency between this Regulation and the rules applicable to credit institutions regulated under Directive 2013/36/EU of the European Parliament and of the Council[56], it is also appropriate to integrate ***certain aspects of*** the conformity assessment procedure and some of the providers' procedural obligations in relation to risk management, post marketing monitoring and documentation into the existing obligations and procedures under Directive 2013/36/EU. In order to avoid overlaps, limited derogations should also be envisaged in relation to the quality management system of providers and the monitoring obligation placed on users of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

[56] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and

repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Or. en

Amendment 756
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 80 a (new)

Text proposed by the Commission	*Amendment*
	(80 a) Where the national market surveillance authority has not taken measures against an infringement to this Regulation, the Commission should be in possession of all the necessary resources, in terms of staffing, expertise, and financial means, for the performance of its tasks instead of the national market surveillance authority under this Regulation. In order to ensure the availability of the resources necessary for the adequate investigation and enforcement measures that the Commission could undertake under this Regulation, the Commission should charge fees on national market surveillance authorities, the level of which should be established on a case-by-case basis. The overall amount of fees charged should be established on the basis of the overall amount of the costs incurred by the Commission to exercise its investigation and enforcement powers under this Regulation. Such an amount should include costs relating to the exercise of the specific powers and tasks connected to Chapter 4 of Title VIII of this Regulation. The external assigned revenues resulting from the fees could be used to finance additional human resources, such as contractual agents and seconded national experts, and other expenditure related to the fulfilment of

these tasks entrusted to the Commission by this Regulation.

Or. en

Justification

Consistent with the new Article on Commission fees.

Amendment 757
Morten Løkkegaard

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) The development of AI systems other than high-risk AI systems in ***accordance with the requirements of this Regulation*** may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct ***intended to foster the voluntary application of the mandatory*** requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data.	(81) The development of AI systems other than high-risk AI systems in ***a safe, trustworthy, and ethical manner*** 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 ***voluntary market-based*** codes of conduct ***based on the*** requirements applicable to high-risk AI systems***, adapted in light of the intended purpose of the systems and the lower risk involved***. 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. ***Compliance with the codes of conduct can be signaled through a label, where relevant. The Digital Europe Programme should support the development and uptake of these codes of conduct.*** 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

Justification

Voluntary codes of conduct can be an important tool to foster safe, trustworthy, and ethical application of all AI systems. For the codes of conduct to be relevant and appropriate for non-high-risk AI systems they should however not oblige the companies to live up to all high-risk requirements in Chapter 2. This amendment seeks to introduce more flexibility for the code of conduct to be adapted to the lower risk involved in non-high-risk applications. In addition, it is suggested to specify that compliance with the codes of conduct can be signaled through a label. In this way the codes of conduct can be a stepping-stone for providers, particularly the small ones, as well as a tool for users to identify providers that apply safe, trustworthy, and ethical AI, hence driving a market-based transition towards more safe, trustworthy, and ethical use of AI.The Digital Europe Programme is an important instrument to support the development of the voluntary codes of conduct.

Amendment 758
Christel Schaldemose

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) The development of AI systems other than high-risk AI systems in ***accordance with the requirements of this Regulation*** may lead to a larger uptake of trustworthy artificial intelligence in the Union. Providers of non-high-risk AI systems should be encouraged to create codes of conduct ***intended to foster the voluntary application of the mandatory*** requirements applicable to high-risk AI systems. Providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams. The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical	(81) The development of AI systems other than high-risk AI systems in ***a safe, trustworthy and ethical manner*** 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 ***voluntary market-based*** codes of conduct ***based on the*** requirements applicable to high-risk AI systems***, adapted in light of the intended purpose of the systems and the lower risk involved***. 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. ***Compliance with the codes of conduct can be signaled through a label, where relevant. The Digital Europe Programme should support the development and uptake of these codes of conduct.*** The Commission

interoperability of different types of data.

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

Or. en

Amendment 759
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Svenja Hahn, Morten Løkkegaard, Alin Mituța

Proposal for a regulation
Recital 81

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

interoperability of different types of data.

Or. en

Amendment 760
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 81

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

Or. en

Amendment 761
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä

on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out ***herein*** are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council[57] would apply as a safety net.	(82) It is important that AI systems related to products that are not high-risk in accordance with this Regulation and thus are not required to comply with the requirements set out ***for high-risk AI systems*** are nevertheless safe when placed on the market or put into service. To contribute to this objective, the Directive 2001/95/EC of the European Parliament and of the Council[57] would apply as a safety net.
[57] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).	[57] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

Or. en

Amendment 762
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 83

Text proposed by the Commission	*Amendment*
(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks.	(83) In order to ensure trustful and constructive cooperation of competent authorities on Union and national level, all parties involved in the application of this Regulation should ***aim for transparency and openness. Where necessary for individual cases and internal deliberations, they should also*** respect the confidentiality of information and data obtained in carrying out their tasks.

Or. en

Amendment 763
Axel Voss, Deirdre Clune

Proposal for a regulation
Recital 84

Text proposed by the Commission	*Amendment*
(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation.	(84) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation. ***The penalties and litigation costs under this Regulation should not be subject to contractual clauses or any other arrangements.***

Or. en

Amendment 764
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Recital 84 a (new)

Text proposed by the Commission	*Amendment*
	(84 a) In order to strengthen and harmonise administrative penalties for infringements of this Regulation, each national supervisory authority should have the power to impose administrative fines. This Regulation should indicate infringements and the upper limit for setting the related administrative fines, which should be determined by the

national supervisory authority in each individual case, taking into account all relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of its consequences and the measures taken to ensure compliance with the obligations under this Regulation and to prevent or mitigate the consequences of the infringement.

Or. en

Amendment 765
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 84 a (new)

Text proposed by the Commission	*Amendment*
	(84 a) An affected person should also have the right to mandate a not-for-profit body, organisation or association that has been properly constituted in accordance with the law of a Member State, to lodge the complaint on their behalf. To this end, Directive 2020/1828/EC on Representative Actions for the Protection of the Collective Interests of Consumers should be amended to include this Regulation among the provisions of Union law falling under its scope.

Or. en

Justification

Consistent with the new Articles 68 a and b.

Amendment 766
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Recital 84 a (new)

Text proposed by the Commission	*Amendment*
	(84 a) Union legislation on the protection of whistleblowers (Directive (EU) 2019/1937) has full application to academics, designers, developers, project contributors, auditors, product managers, engineers and economic operators acquiring information on breaches of Union law by a provider of AI system or its AI system, even if they are not explicitly mentioned in Article 4(1)a-4(1)d of that Directive.

Or. en

Amendment 767
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation
Recital 84 b (new)

Text proposed by the Commission	*Amendment*
	(84 b) Natural persons, affected by an AI system falling within the scope of this Regulation, should have the right to lodge a complaint against the providers or users of such AI system with a national supervisory authority, if they consider that their fundamental rights, health or safety have been breached. An affected person should also have the right to mandate a not-for-profit body, organisation or association that has been properly constituted in accordance with the law of a Member State, to lodge the complaint on their behalf.

Or. en

Amendment 768
Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Recital 84 b (new)

Text proposed by the Commission	*Amendment*
	(84 b) Union legislation on consumer protection(notably Directives (EU) 2019/2161, 2005/29/EC,2011/83/EU) applies to AI systems to the extent determined in these legislations, regardless of whether these systems are categorized as high-risk.

Or. en

Amendment 769
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Recital 85

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

including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	***Commission should only be able to adopt such delegated acts to include non-restrictive additions or clarifications in the lists in those Annexes, whereas deletions, restrictive clarifications or amendments to the definitions of the items in those Annexes should only result from the adoption of amending regulations.*** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
[58] OJ L 123, 12.5.2016***, p. 1***.	[58] OJ L 123, 12.5.2016 ***p.1***.

Or. fr

Amendment 770
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Recital 85

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

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

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

importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

Or. en

Justification

To create legal certainty for AI developers, it is important that the high-risk areas of application are clearly laid down and cannot be changed quickly and dramatically by means of delegated acts. All additions to the list of high risk AI systems should be subject to Parliament's approval.

Amendment 771
Kim Van Sparrentak, Sergey Lagodinsky, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . ***These consultations should involve the participation of a balanced selection of stakeholders, including consumer organisations, associations representing affected persons, businesses representatives from different sectors and sizes, as well as researchers and scientists.*** In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
[58] OJ L 123, 12.5.2016, p. 1.	[58] OJ L 123, 12.5.2016, p. 1.

Or. en

Amendment 772
Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend ***the techniques and approaches referred to in Annex I to define AI systems,*** the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V**,** the provisions regarding the conformity assessment procedures in Annex VI and VII ***and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply***. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	(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 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 ***and*** the provisions regarding the conformity assessment procedures in Annex VI and VII. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

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

Or. en

Justification

Consistent with the deletion of Annex I and the changes in Article 43.

Amendment 773
Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuță, Ramona Strugariu, Dragoş 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	*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-Making[58] . In particular, to ensure equal participation in	(85) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the techniques and approaches referred to in Annex I to define AI systems, the Union harmonisation legislation listed in Annex II, the high-risk AI systems listed in Annex III, the provisions regarding technical documentation listed in Annex IV, the content of the EU declaration of conformity in Annex V, the provisions regarding the conformity assessment procedures in Annex VI and VII and the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation should apply. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including ***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-Making[58] . 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.

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