AI ACT - COMPROMISE AMENDEMENTS - BATCH 6 - V3- 21.02.2023

TITLE 1 - General provisions

COMP 1a:

Covers: AMs 47, 48, 49 (Rapp), 780 (S&D), 781 (TheLeft), 782 (RE), 783 (Greens), 784 (S&D), 788 (TheLeft), 789 (S&D), 790 (S&D), 792 (S&D), 793 (S&D), 794 (S&D), 795 (Greens), 796 (RE), 797 (RE), 798 (Greens), 799 (EPP), 800 (EPP), 801 (EPP), 802 (RE), 803 (RE), 804 (EPP), 805 (RE), 806 (EPP), 809 (TheLeft), CULT 25, TRAN 30, TRAN 31, JURI 22, JURI 23, JURI 24, JURI 25, JURI 26

Falls: AMs 779 (RE), 785 (ID), 786 (Greens), 787 (EPP), 791 (EPP), 807 (RE), 808 (Greens), 810 (TheLeft), 811 (S&D), 812 (TheLeft), 813 (TheLeft), ENVI 54

Parked: AM 790

Article 1
Subject matter

The purpose of this Regulation is to promote the uptake of human centric and trustworthy artificial intelligence and to ensure a high level of protection of health, safety, fundamental rights, democracy and rule of law, and the environment from harmful effects of artificial intelligence systems in the Union while supporting innovation (AMs 780, 781, 782, 783, 784, 786, 787, 809, JURI 22, JURI 25)

This Regulation lays down:

a) harmonised rules for the placing on the market, the putting into service and the use of ***(AMs 786, 787, JURI 22)*** artificial intelligence systems ('AI systems') in the Union ***(AMs 47, 788, 789)***;

b) prohibitions of certain artificial intelligence practices;

c) specific Article 8 Compliance with the requirements and obligations for operators of such systems;

d) harmonised transparency rules for ***certain*** AI systems ~~***intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content***~~ ***(AM 49, 794, 795, 796, CULT 25, JURI 23)***

e) rules on market monitoring ~~***and***~~ ***market*** surveillance***, governance and enforcement (AM 797, 798, 799, TRAN 30, JURI 24)***

(ea) measures to support innovation, with a particular focus on SMEs and start-ups, including on setting up regulatory sandboxes and targeted measures to reduce the regulatory burden on SMEs and start-ups (AM 800, 801, 802, 804, 805, TRAN 31, JURI 26)

Obtenu par CONTEXTE

(eb) rule for the establishment and functioning of the European Union artificial intelligence Office (AM 803, 806, JURI 27).

COMP 1b

Covers: AMs 50, 51, 52, 53, 54 (Rapp), 814 (TheLeft), 816 (S&D), 818 (EPP), 820 (RE), 821 (S&D), 823 (TheLeft), 825 (S&D), 826 (Greens), 827 (RE), 829 (Greens), 830 (EPP), 831 (S&D), 832 (S&D), 833 (RE), 835 (S&D), 837 (RE), 838 (RE), 839 (TheLeft), 840 (S&D), 843 (EPP), 844 (RE), 845 (RE), 846 (EPP), 847 (RE), 848 (EPP), 849 (RE), 850 (EPP), 851 (RE), 852 (EPP), 853 (RE), 854 (EPP), 855 (EPP), 856 (RE), 857 (RE), 858 (EPP), 859 (EPP), 860 (RE), 861 (RE), 863 (RE), 872 (S&D), 874 (EPP), 876 (S&D), 883 (RE), 887 (ECR), 888 (EPP), 891 (S&D), 892 (EPP), 893 (Greens), 895 (ECR), 896 (TheLeft), 897 (S&D), 898 (Greens), 900 (TheLeft), 902 (RE), TRAN 32 to 40, TRAN 41, TRAN 42, TRAN 43, JURI 28, JURI 30, JURI 31, JURI 33, ITRE 18, ITRE 19, CULT 26
Falls: AMs 815 (Greens), 817 (TheLeft), 819 (Greens), 822 (EPP), 824 (EPP), 828 (RE), 834 (RE), 836 (Greens), 841 (TheLeft), 842 (EPP), 864 (Greens), 865 (TheLeft), 866 (TheLeft), 867 (S&D), 868 (RE), 869 (EPP), 870 (ECR), 871 (ECR), 873 (TheLeft), 875 (EPP), 877 (ID), 878 (S&D), 879 (Greens), 880 (TheLeft), 881 (RE), 882 (S&D), 884 (ECR), 885 (TheLeft), 886 (TheLeft), 889 (Greens), 890 (S&D), 894 (TheLeft), 899 (TheLeft), 901 (TheLeft), JURI 34
Parked: AMs 862 (mix), 824 (EPP) +JURI 29

Article 2
Scope

1. This Regulation applies to:

(a) providers placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country; ***(AM 50, 816)***

(b) ~~users~~ ***deployers*** of AI systems ***that have their place of establishment or who are*** located within the Union ***(AM 818, 820, 821, JURI 28)***;

(c) providers ***and deployers*** of AI systems ***that have their place of establishment or*** are located in a third country, where ***either Member State law applies by virtue of a public international law or*** the output produced by the system is ***intended to be*** used in the Union ***(AM 51, 825, 826, 827)***;

(ca) providers placing on the market or putting into service AI systems referred to in Article 5 outside the Union where the provider or distributor of such systems is located within the Union (AM 835, 838)

(cb) importers, distributors of AI systems and authorised representatives of providers of AI systems which that have their establishment or are located in the Union (AMs 829, 830, 833, 837, JURI 30)

(cc) affected ~~natural~~ persons that are located in the Union and whose health, safety or fundamental rights were adversely impacted ~~affected~~ by the use of

Obtenu par CONTEXTE

an AI system that was placed on the market or put into service in the Union (AM 52, 823, 831, 832)

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

~~(a) Regulation (EC) 300/2008;~~

~~(b) Regulation (EU) No 167/2013;~~

~~(c) Regulation (EU) No 168/2013;~~

~~(d) Directive 2014/90/EU;~~

~~(e) Directive (EU) 2016/797;~~

~~(f) Regulation (EU) 2018/858;~~

~~(g) Regulation (EU) 2018/1139;~~

~~(h) Regulation (EU) 2019/2144.~~ (AM 843 to 860 + TRAN 32 to 40 + JURI 31)

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

4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international ***cooperation or*** agreements for law enforcement and judicial cooperation with the Union or with one or more Member States ***and are subject of a decision of the Commission adopted in accordance with Article 36 of Directive (EU)2016/680 or Article 45 of Regulation 2016/679 (adequacy decision) or are part of an international agreement concluded between the Union and that third country or international organisation pursuant to Article 218 TFUE providing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals (AM 883)***.

5. This Regulation shall not affect the application of the provisions on the liability of intermediary service providers set out in Chapter II, Section IV of Directive 2000/31/EC of the European Parliament and of the Council[1] [*as to be replaced by the corresponding provisions of the Digital Services Act*].

5a. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processes in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulations (EU)2016/679, (EU) 2018/1725, Directive 2002/58/EC and (EU) 2016/680 without prejudice to arrangements provided for in ~~with the exception of~~ Article 54 of this Regulation (AM 54, 872, 893,896, TRAN 43, 814)

[1] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

Obtenu par CONTEXTE

5b. ***This Regulation is without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety.***

5c. ***This regulation shall not preclude Member States or the Union from maintaining or introducing laws, regulations or administrative provisions which are more favourable to workers in terms of protecting their rights in respect of the use of AI systems by employers, or to encourage or allow the application of collective agreements which are more favourable to workers.***

5d. ***This Regulation shall not apply to research, testing and development activities regarding an AI system prior to this system being placed on the market or put into service, provided that these activities are conducted respecting fundamental rights and the applicable Union law. The testing in real world conditions shall not be covered by this exemption. The Commission is empowered to ~~may~~ adopt delegated acts in accordance with Article 73 ~~that clarify the application of this paragraph~~ to specify this exemption to prevent its existing and potential abuse. The AI Office shall provide guidance on the governance of research and development pursuant to Article 56, also aiming at coordinating its application by the national supervisory authorities (JURI 33).***

5e. ***This Regulation shall not apply to AI components provided under free and open-source licences except to the extent they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV. This exemption ~~should~~ shall not apply to ~~advanced~~ foundation models as defined in Art 3(xx).***

COMP 1c on matching recitals

Covers: AMs 1, 2, 3, 4, 5, 6, 7, 11, 12, 13 (Rapp), 310 (EPP), 311 (RE), 312 (EPP), 313 (Greens), 314 (S&D), 316 (S&D), 318 (TheLeft), 324 (S&D), 325 (S&D), 327 (S&D), 331 (EPP), 335 (S&D), 336 (TheLeft), 337 (EPP), 344 (EPP), 345 (S&D), 346 (EPP), 347 (Greens), 348 (RE), 349 (EPP), 350 (S&D), 351 (TheLeft), 352 (EPP), 353 (EPP), 354 (ECR), 356 (EPP); 387 (Greens), 388 (EPP), 393 (RE); 399 (RE); 402 (S&D), 405 (S&D); 407 (The Left), 408 (Greens), 409 (S&D), 897 (S&D); 898 (Greens), ***TRAN 1, TRAN 5, CULT 1, CULT 2, CULT 3, CULT 4, CULT 5, CULT 9, ENVI 1, ENVI 3, ENVI 5, ENVI 6, ENVI 14, ENVI 16, ITRE 4, JURI 1, JURI 2, JURI 3, JURI 5, JURI 14, TRAN 8,***

Falls: AMs 10 (Rapp); 315 (ECR), 317 (ID), 320 (Greens), 321 (ECR), 322 (TheLeft), 323 (ID), 326 (S&D), 328 (EPP), 329 (EPP), 333 (TheLeft), 339 (S&D), 340 (TheLeft), 355 (EPP), 389 (ID), 390 (S&D), 391 (S&D); 392 (Greens); 394 (EPP); 394 (EPP); 395 (S&D); 296 (The Left); 397 (Greens); 398 (ID); 410 (ID), ***ENVI 2, ENVI 4, ENVI 7, ENVI 8, ENVI 9, ENVI 10, ENVI 17, ITRE 1, TRAN 3, TRAN 4, TRAN 5, TRAN 9***
Parked: 319 (Greens) fall under recital for AI definition

Having regard to the opinion of the European Central Bank, (310, 311)

Object pat CONTEXTE

Having regard to the joint opinion of the European Data Protection Board and the European Data Protection Supervisor, (312)

(1) The purpose of this Regulation is ***to promote the uptake of human centric and trustworthy artificial intelligence and to ensure a high level of protection of health, safety, fundamental rights, democracy and rule of law and the environment from harmful effects of artificial intelligence systems in the Union while supporting innovation and improving*** ~~***to improve***~~ the functioning of the internal market. ***This Regulation lays*** ~~***by laying***~~ down a uniform legal framework in particular for the development, ~~***marketing and***~~ ***the placing on the market, the putting into service and the*** use of artificial intelligence in conformity with Union ***principles and*** values ~~. This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety, fundamental rights, and it~~ ***and*** ensures the free movement of AI-based goods and services cross-border, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation ***(AM 1, 313, 314, 316, 318, CULT 1, CULT 4, JURI 1, ENVI 1, TRAN 1). Certain AI systems can also have an impact on democracy and rule of law and the environment. For the purposes of this Regulation, these concerns are specifically addressed in the critical sectors and use cases listed in Annex III Point 8, and in Art 15a and Annex IV point 3b respectively.***

1b) This Regulation should preserve the values of the Union facilitating the distribution of artificial intelligence benefits across society, protecting individuals, companies, democracy and rule of law and the environment from risks while boosting innovation and employment and making Europe a leader in the field (ENVI 3).

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

Obtenu par COMTRACE

~~*Article 16 TFEU, it is appropriate to consult the European Data Protection Board.*~~ ***(AM 2, CULT 2)***

(2a) As artificial intelligence often relies on the processing of large volumes of data, and many AI systems and applications on the processing of personal data, it is appropriate to base this Regulation on Article 16 TFEU, which enshrines the right ~~of everyone~~ to the protection of natural persons with regard to the processing of personal data ~~concerning them~~ and provides for the adoption of rules on the protection of individuals with regard to the processing of personal data. (AM 3, 324)

(2b) The fundamental right to the protection of personal data is safeguarded in particular by Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive 2016/680. Directive 2002/58/EC additionally protects private life and the confidentiality of communications, including providing conditions for any personal and non-personal data storing in and access from terminal equipment. Those legal acts provide the basis for sustainable and responsible data processing, including where datasets include a mix of personal and nonpersonal data. This Regulation complements and does not affect Union law on data protection and privacy, in particular those other Regulations and Directives. This Regulation does not seek to affect the application of existing Union law governing the processing of personal data, including the tasks and powers of the independent supervisory authorities competent to monitor compliance with those instruments. This Regulation does not affect the fundamental rights to private life and data protection as provided for by Union law on data protection and privacy and enshrined in the Charter of Fundamental Rights of the European Union (the 'Charter') (AM 4, 327, 354)

(2c) This Regulation is also without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety, including ~~including~~ Regulation (EU) 2017/2394, Regulation (EU) 2019/1020 and Directive 2001/95/EC on general product safety and Directive 2013/11/EU. (AMs 897, 898)

(2d) In line with Article 114(2) TFEU, this Regulation does not affect the rights and interests of employed persons. This Regulation should therefore not affect Community law on social policy and national labour law and practice, that is any legal and contractual provision concerning employment conditions, working conditions, including health and safety at work and the relationship between employers and workers, including information, consultation and participation. This Regulation should not affect the exercise of fundamental rights as recognized in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States, in accordance with national law and/or practice. Nor should it affect concertation practices, the right to negotiate, to conclude and enforce collective agreement or to take collective action in accordance with national law and/or practice. It should in any case not prevent the Commission from proposing specific legislation on the rights and freedoms of workers affected by AI systems (AM 325)

Obtenu par COYTEXTE

(2e) This Regulation should not affect the provisions aimed at improving working conditions in platform work set out in Directive 2021/762/EC. (AM 405)

(2f) This Regulation should help in supporting research and innovation and should not undermine research and development activity and ~~should~~ respect freedom of ~~science~~ scientific research. It is therefore necessary to exclude from its scope AI systems specifically developed and put into service in the course of and for the sole purpose of scientific research and development and to ensure that the Regulation does not otherwise affect scientific research and development activity on AI systems. ~~As regards product oriented research and development activity by providers, the provisions of this Regulation should apply insofar as such research leads to or entails placing of an AI system on the market or putting it into service~~. Under all circumstances, any research and development activity should be carried out in accordance with the Charter of fundamental rights, Union law as well as the law of the Member States ~~recognised ethical standards for scientific research~~. (AM 399, ITRE 4, TRAN 8)

(3) Artificial intelligence is a fast evolving family of technologies that ***is already and*** can contribute to a wide array of economic, ***environmental*** and societal benefits across the entire spectrum of industries and social activities ***if developed in accordance with relevant general principles in line with the EU Charter of Fundamental Rights and the values on which the Union is founded (JURI 2)***. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, ***food safety,*** education and training, ***media, sports, culture,*** infrastructure management, energy, transport and logistics, ***crisis management,*** public services, security, justice, resource and energy efficiency, ***environmental monitoring, the conservation and restoration of biodiversity and econsystems,*** and climate change mitigation and adaptation ***(CULT 3, ENVI 5)***.

(3a) ~~In order for Member States~~ To contribute to reaching the carbon neutrality targets, European companies should seek to utilise all available technological advancements that can assist in realising this goal. Artificial Intelligence is a well-developed and ready-to-use technology that can be used to process the ever-growing amount of data created during industrial, environmental, health and other processes. To facilitate investments in AI-based analysis and optimisation tools ~~solutions~~, this Regulation should provide a predictable and proportionate environment for low-risk industrial solutions (331).

(4) At the same time, depending on the circumstances regarding its specific application and use, ***as well as the level of technological development,*** artificial intelligence may generate risks and cause harm to public ***or private*** interests and ***fundamental*** rights ***of natural persons*** that are protected by Union law. Such harm might be material or immaterial, ***including physical, psychological, societal or economic harm (AM 5, 334, 335, 336, 337, ENVI 6, JURI 3).***

Obtained by Contexte

(4a) Given the major impact that artificial intelligence can have on society and the need to build trust, it is vital for artificial intelligence and its regulatory framework to be developed according to Union values enshrined in Article 2 TEU, the fundamental rights and freedoms enshrined in the Treaties, the Charter, and international human rights law. As a pre-requisite, artificial intelligence should be a human-centric technology. It should not substitute human autonomy or assume the loss of individual freedom and should primarily serve the needs of ~~the people~~ society and the common good. Safeguards should be provided to ensure the development and use of ethically embedded artificial intelligence that respects Union values and the Charter (AM 6).

(5) A Union legal framework laying down harmonised rules on artificial intelligence is therefore needed to foster the development, use and uptake of artificial intelligence in the internal market that at the same time meets a high level of protection of public interests, such as health and safety, ***~~and~~*** the protection of fundamental rights, ***democracy and rule of law and the environment,*** as recognised and protected by Union law. To achieve that objective, rules regulating the ***development, the*** placing on the market, ***the ~~and~~*** putting into service ***and the use*** of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. ***These rules should be clear and robust in protecting fundamental rights, ~~of all actors and~~ supportive of ~~to~~ new innovative solutions, ~~thus~~ and enabling to a European ecosystem of public and private actors creating AI systems in line with EU values.*** By laying down those rules ***as well as measures in support of innovation with a particular focus on SMEs and start-ups***, this Regulation supports the objective of ***promoting the "AI made in Europe, of*** the Union of being a global leader in the development of secure, trustworthy and ethical artificial intelligence, as stated by the European Council[2], and it ensures the protection of ethical principles, as specifically requested by the European Parliament[3]. ***(AM 7, 344, 345, 346, 347, 348, 349, 350, 351, 352, CULT 5, TRAN 5, ENVI 14).***

5a. Furthermore, in order to foster the development of artificial intelligence systems in line with Union values, the Union needs to address the main gaps and barriers blocking the potential of the digital transformation including the shortage of digitally skilled workers, cybersecurity concerns, lack of investment and access to investment, and existing and potential gaps between large companies, SME's and start-ups. Special attention should be paid to ensuring that the benefits of AI and innovation in new technologies are felt across all regions of the Union and that sufficient investment and resources are provided especially to those regions that may be lagging behind in some digital indicators (AM 353)

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

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

Obtenu par CONTEXTE

(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union ***and on international level (AM 388)***, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to ~~users~~ ***deployers (AM 387)*** of AI systems established within the Union. ***In order for the European Union to be true to its fundamental values, AI systems intended to be used for practices that are considered unacceptable by this Regulation, should be equally be deemed unacceptable outside the EU because of their particularly harmful effect to fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union. Therefore it is appropriate to prohibit the export of such AI systems to third countries by providers residing in the Union.***

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and ~~users~~ ***deployers*** of AI systems that are established in a third country, to the extent the output produced by those systems is ***intended to be*** used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations. ***This exception should nevertheless be limited to trusted countries and international organisation that share Union values. (AM 393)***

(12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or ~~user~~ ***deployer*** of an AI system. AI systems exclusively developed or used for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V of the Treaty on the European Union (TEU). This Regulation should be without prejudice to the provisions regarding the liability

Obtenu par COUTEXTE

of intermediary service providers set out in Directive 2000/31/EC of the European Parliament and of the Council [as amended by the Digital Services Act].

12a. ***Software and data that are openly shared and where users can freely access, use, modify and redistribute them or modified versions thereof, can contribute to research and innovation in the market. Research by the European Commission also shows that free and open-source software can contribute between €65 billion to €95 billion to the European Union's GDP and that it can provide significant growth opportunities for the European economy. Users are allowed to run, copy, distribute, study, change and improve software and data, including models by way of free and open-source licences. To foster the development and deployment of AI, especially by SMEs, start-ups, academic research but also by individuals, this Regulation should not apply to such free and open-source AI components except to the extent that they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV of this Regulation.***

12b. ***Neither the collaborative development of free and open-source AI components nor making them available on open repositories should constitute a placing on the market or putting into service. A commercial activity, within the understanding of making available on the market, might however be characterised by charging a price, with the exception of transactions between micro enterprises, for a free and open-source AI component but also by charging a price for technical support services, by providing a software platform through which the provider monetises other services, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software.***

12c. ***The developers of free and open-source AI components should not be mandated under this Regulation to comply with requirements targeting the AI value chain and, in particular, not towards the provider that has used that free and open-source AI component. Developers of free and open-source AI components should however be encouraged to implement widely adopted documentation practices, such as model and data cards, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the EU.***

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights ***as well as democracy and rule of law and the environment***, ***(AMs 13, 408, 409, CULT 9, ENVI 16, JURI 5)*** common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) ***the European Green Deal (The Green Deal), the Joint Declaration on Digital Rights of the Union (the Declaration) and the Ethics Guidelines for Trustworthy Artificial Intelligence (AI) of the High-Level Expert Group on Artificial Intelligence (AI HLEG), (AM 407)*** and should be non-discriminatory and in line with the Union's international trade commitments.

Obtenu par CONTEXTE

Matching recitals

Covered: AMs 8 (Rapp); 9 (Rapp); 357 (EPP); 358 (RE); 359 (S&D); 360 (S&D); 364 (EPP); 367 (The Left); 368 (The Left); 369 (S&D); 370 (Greens); 371 (S&D); 372 (S&D); 374 (RE); 375 (RE); 376 (EPP); 377 (ECR); 380 (Greens);
Falls: 361 (ID); 362 (Greens); 363 (EPP); 365 (EPP); 366 (EPP); 373 (Greens); 378 (Greens); 379 (EPP); 381 (ID); 382 (S&D); 383 (S&D); 384 (The Left);
Parked:

(6) The notion of AI system ***in this Regulation*** should be clearly defined ***and closely aligned with the work of international organisations working on artificial intelligence*** to ensure legal certainty***, harmonization and wide acceptance***, while providing the flexibility to accommodate ***the rapid*** technological developments ***in this field***. ***Moreover, it*** should be based on key characteristics of artificial intelligence, ***such as its learning, reasoning or modelling capabilities, so as to distinguish it from simpler software systems or programming approaches. AI systems~~, within the meaning of this Regulation~~, are designed to operate with varying levels of autonomy, meaning that they have at least some degree of independence of actions from human controls and of capabilities to operate without human intervention. The term "machine-based" refers to the fact that AI systems run on machines. The reference to explicit or implicit objectives underscores that AI systems can operate according to explicit human-defined objectives or to implicit objectives. The objectives of the AI system may be different from the intended purpose of the AI system in a specific context. The reference to predictions includes content, which is considered in this Regulation a form of prediction as one of the possible outputs produced by an AI system. For the purposes of this Regulation, environments should be understood as the contexts in which the AI systems operate, whereas outputs generated by the AI system, meaning predictions, recommendations or decisions, respond to the objectives of the system, on the basis of inputs from said environment. Such output further influences said environment, even by merely introducing new information to it.***

(6a) (new). AI systems often have machine learning capacities that allow them to adapt and perform new tasks autonomously. Machine learning refers to the computational process of optimizing the parameters of a model from data, which is a mathematical construct generating an output based on input data. Machine learning approaches include, for instance, supervised, unsupervised and reinforcement learning, using a variety of methods including deep learning with neural networks. This Regulation is aimed at addressing new potential risks that may arise by delegating control to AI systems, in particular to those AI systems that can evolve after deployment. The function and outputs of many of these AI systems are based on abstract mathematical relationships that are difficult for humans to understand, monitor and trace back to specific inputs. These complex and opaque characteristics (black box element) impact accountability and explainability. Comparably simpler techniques such as knowledge-based approaches, Bayesian estimation or decision-trees may also lead to legal gaps that need to be addressed by this Regulation, in particular when they are used in combination with machine learning approaches in hybrid systems.

(6b) (new) AI systems can be used as stand-alone ***software system***, integrated into a physical product (embedded), used to serve the functionality of a physical product without being integrated therein (non-embedded) or ***used as an AI component of a larger system. If this larger system would not function without the AI component in question, then the entire larger system should be considered as one single AI system under this Regulation.***

(XX) Open source

Software and data that are openly shared and where users can freely access, use, modify and redistribute them or modified versions thereof, can contribute to research and innovation in the market. Research by the European Commission also shows that free and open-source software can contribute between €65 billion to €95 billion to the European Union's GDP and that it can provide significant growth opportunities for the European

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economy. Users are allowed to run, copy, distribute, study, change and improve software and data, including models by way of free and open-source licences. To foster the development and deployment of AI, especially by SMEs, start-ups, academic research but also by individuals, this Regulation should not apply to such free and open-source AI components except to the extent that they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV of this Regulation.

Neither the collaborative development of free and open-source AI components nor making them available on open repositories should constitute a placing on the market or putting into service. A commercial activity, within the understanding of making available on the market, might however be characterised by charging a price, with the exception of transactions between micro enterprises, for a free and open-source AI component but also by charging a price for technical support services, by providing a software platform through which the provider monetises other services, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software.

The developers of free and open-source AI components should not be mandated under this Regulation to comply with requirements targeting the AI value chain and, in particular, not towards the provider that has used that free and open-source AI component. Developers of free and open-source AI components should however be encouraged to implement widely adopted documentation practices, such as model and data cards, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the EU.

(7) The notion of biometric data used in this Regulation is in line with and should be interpreted consistently with the notion of biometric data as defined in Article 4(14) of Regulation (EU) 2016/679 of the European Parliament and of the Council[4], ~~Article 3(18) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[5] and Article 3(13) of Directive (EU) 2016/680 of the European Parliament and of the Council[6].~~ ***(AM 369). Biometrics-based data are additional data resulting from***

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[4] 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).

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

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

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specific technical processing relating to physical, physiological or behavioural signals of a natural person, such as facial expressions, movements, pulse frequency, voice, key strikes or gait, which may or may not allow or confirm the unique identification of a natural person. (AMs 9, 367, 368, 370)

(7a) The notion of biometric identification as used in this Regulation should be defined as the automated recognition of physical, physiological, behavioural, and psychological human features such as the face, eye movement, facial expressions, body shape, voice, speech, gait, posture, heart rate, blood pressure, odour, keystrokes, psychological reactions (anger, distress, grief, etc.) for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification), irrespective of whether the individual has given its consent or not (AM 373, 378).

(8) The notion of remote biometric identification system as used in this Regulation should be defined functionally, as an AI system intended for the identification of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge whether the targeted person will be present and can be identified, irrespectively of the particular technology, processes or types of biometric data used***, exlcuding authentication and verification systems which merely compare the biometric data of an individual to their previously provided biometric data (one-to-one)***. Considering their different characteristics and manners in which they are used, as well as the different risks involved, a distinction should be made between 'real-time' and 'post' remote biometric identification systems. In the case of 'real-time' systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the 'real-time' use of the AI systems in question by providing for minor delays. 'Real-time' systems involve the use of 'live' or 'near-'live' material, such as video footage, generated by a camera or other device with similar functionality. In the case of 'post' systems, in contrast, the biometric data have already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned. ***Given that the notion of biometric identification is independent from the individual's consent, this definition applies even when warning notices are placed in the location that is under surveillance of the remote biometric identification system, and is not de facto annulled by pre-enrolment (AMs 373, 374, 375, 376, 377, 378)***

(9) For the purposes of this Regulation the notion of publicly accessible space should be understood as referring to any physical place that is accessible to the public, irrespective of whether the place in question is privately or publicly owned. Therefore, the notion does not cover places that are private in nature and normally not freely accessible for third parties, including law enforcement authorities, unless those parties have been specifically invited or authorised, such as homes, private clubs, offices, warehouses and factories. Online spaces are not covered either, as they are

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not physical spaces. However, the mere fact that certain conditions for accessing a particular space may apply, such as admission tickets or age restrictions, does not mean that the space is not publicly accessible within the meaning of this Regulation. Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, ***sports grounds, schools, universities, relevant parts of hospitals and banks, amusement parks, festivals,*** shops and shopping centres are normally also publicly accessible. Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand. ***(AM 380)***

(10) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union ***and on international level (AM 388)***, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to ~~users~~ ***deployers (AM 387)*** of AI systems established within the Union. ***In order for the European Union to be true to its fundamental values, AI systems intended to be used for practices that are considered unacceptable by this Regulation, should be equally be deemed unacceptable outside the EU because of their particularly harmful effect to fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union. Therefore it is appropriate to prohibit the export of such AI systems to third countries by providers residing in the Union.***

(11) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are neither placed on the market, nor put into service, nor used in the Union. This is the case for example of an operator established in the Union that contracts certain services to an operator established outside the Union in relation to an activity to be performed by an AI system that would qualify as high-risk and whose effects impact natural persons located in the Union. In those circumstances, the AI system used by the operator outside the Union could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and ~~users~~ ***deployers*** of AI systems that are established in a third country, to the extent the output produced by those systems is used in the Union. Nonetheless, to take into account existing arrangements and special needs for cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of international agreements concluded at national or European level for law enforcement and judicial cooperation with the Union or with its Member States. Such agreements have been concluded bilaterally between Member States and third countries or between the European Union, Europol and other EU agencies and third countries and international organisations. ***This exception should nevertheless be***

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limited to trusted countries and international organisation that share Union values. (AM 393)

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

~~*(12a) AI systems developed or used exclusively for military purposes should be excluded from the scope of this Regulation where that use falls under the exclusive remit of the Common Foreign and Security Policy regulated under Title V TEU. However, AI systems which are developed or used for military purposes but can also be used for civil purposes, falling under the definition of "dual use items" pursuant to Regulation (EU) 2021/821 of the European Parliament and of the Council[46] should fall into the scope of this Regulation. (AMs 402; 403)*~~

(13) In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights ***as well as democracy and rule of law and the environment****, (AMs 13, 408, 409)* common normative standards for all high-risk AI systems should be established. Those standards should be consistent with the Charter of fundamental rights of the European Union (the Charter) ***the European Green Deal (The Green Deal), the Joint Declaration on Digital Rights of the Union (the Declaration) and the Ethics Guidelines for Trustworthy Artificial Intelligence (AI) of the High-Level Expert Group on Artificial Intelligence (AI HLEG), (AM 407)*** and should be non-discriminatory and in line with the Union's international trade commitments.

BATCH 12 (Articles 3, 4 and Annex I + matching recitals)

CA XXXX - Changes compared to the last version are marked in **green**

Covers: **56 (Rapp.); ~~58 (Rapp~~); 59 (Rapp); 60 (Rapp); 73 (Rapp); 928 (EPP) 937 (RE); 938 (EPP); 939 (RE); 944 (ECR); 945 (EPP); 946 (Greens); 947 (RE); 948 (Greens); 951 (S&D); 958 (Greens); 960 (S&D); 961 (S&D); 963 (Greens); 973 (EPP); 974 (EPP); 975 (ECR); 976 (Greens); 977 (The Left); 978 (S&D); 980 (EPP); 982 (EPP), 985 (The Left), 986 (EPP); 989 (Greens); 992 (Greens); 998 (EPP); 999 (S&D); 1000 (EPP); 1002 (RE); 1007 (EPP); 1009 (RE); 1010 (EPP); 1012 (EPP); 1016 (The Left); 1017 (Greens); 1019 (S&D); 1025 (The Left); 1026 (The Left); 1027 (Greens); 1028 (RE); 1029 (S&D); 1031 (The Left); 1032 (The Left); 1033 (RE); 1034 (ID); 1035 (EPP); 1036 (S&D); 1037 (RE); 1038 (Greens); 1039 (S&D); 1040 (S&D); 1041 (Greens); 1042 (ID); 1043 (The Left);**

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1044 (RE); 1045 (The Left); 1046 (RE); 1049 (EPP); 1050 (ECR); 1051 (RE); 1052 (RE); 1062 (EPP); 1067 (ECR); 1068 (EPP); 1078 (RE); 1082 (ID); 1090 (The Left); 1092 (The Left); 1094 (ID); 1095 (S&D); 1097 (Greens); 1098 (S&D); 1099 (EPP), 1101 (ECR); 1103 (RE); 1110 (EPP), 1111 (RE), 1114 (S&D);1116 (Left); 1117 (S&D); 1118 (EPP); 1119 (The Left); 1120 (The Left); 1121 (EPP); 1122 (The Left); 1123 (EPP); 1124 (EPP); 1126 (EPP);

Falls: **57 (Rapp); 58 (Rapp); 929 (EPP); 932 (ECR), 933 (EPP); 940 (RE); 941 (ID); 942 (EPP); 943 (Left); 949 (EPP); 950 (ECR); 952 (EPP); 953 (S&D); 955 (EPP); 965 (ID); 956 (EPP); 957 (EPP); 959 (S&D); 972 (EPP); 979 (ID); 981 (EPP), 983 (S&D), 984 (S&D), 987 (EPP); 991 (EPP); 993 (EPP); 997 (Greens); 1001 (EPP); 1003 (Greens); 1006 (ID); 1011 (ID); 1013 (ID); 1018 (EPP); 1020 (The Left); 1021 (EPP); 1023 (Greens); 1024 (ID); 1047 (RE); 1048 (EPP); 1053 (ECR); 1054 (The Left); 1055 (Greens); 1056 (ECR); 1057 (S&D); 1058 (The Left); 1059 (EPP); 1060 (ID); 1061 (RE); ~~1062 (EPP);~~ 1063 (Greens); 1064 (Greens); 1065 (Greens); 1066 (ID); 1069 (Greens); 1070 (ID); 1071 (ID); 1072 (The Left); 1073 (ID); 1074 (The Left); 1077 (S&D); 1079 (EPP); 1080 (S&D); 1081 (Greens); 1083 (EPP); 1084 (EPP); 1085 (ECR); 1086 (The Left); 1088 (EPP); 1089 (S&D); 1091 (The Left); 1093 (ID); 1096 (The Left); 1102 (ID); 1104 (EPP); 1105 (The Left); 1106 (The Left); 1108 (The Left); 1109 (The Left); 1113 (ID); 1115 (ID); 1125 (The Left); 1127 (EPP); 1128 (RE);**

Parked: **930 (RE), 931 (EPP) - general purpose AI, 934 (EPP), 935 (EPP), 936 (EPP); 962 (The Left); 964 (The left); 966 (ECR); 967 (The Left); 968 (S&D); 969 (RE); 970 (The Left); 971 (The left); 988 (The Left); 990 (The Left); 994 (The Left); 995 (The Left); 1004 (S&D); 1005 (The Left); 1008 (The Left); 1107 (S&D); 1112 (S&D); 1120 (The Left); - general purpose Ai/reasonably foreseeable use; 1100 (Greens) - recommender system**

Article 3
Definitions

For the purpose of this Regulation, the following definitions apply:

(1) 'artificial intelligence system' (AI system) means ***a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions, that influence physical or virtual environments.*** ~~software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;~~

(1a) 'risk' means the combination of the probability of an occurrence of ~~a hazard causing~~ harm and the ~~degree of~~ severity of that harm (AMs 73; 928; 939)

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(1b) 'significant risk' means a risk that is significant as a result of the combination of its severity, intensity, probability of occurrence, and duration of its effects, and its the ability to affect an individual, a plurality of persons or to affect a particular group of persons

Recital

(27) High-risk AI systems should only be placed on the Union market***,*** put into service ***or used (AM 19, 525)*** if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law, ***including fundamental rights, democracy, the rule or law or the environment (AM 19, 519, 524, 525, 527, 528)***. ***In order to ensure alignment with sectoral legislation and avoid duplications, requirements for high-risk AI systems should take into account sectoral legislation laying down requirements for high-risk AI systems included in the scope of this Regulation, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices or Directive 2006/42/EC on Machinery (AM 521, 522).*** AI systems identified as high-risk should be limited to those that have a significant ***risk of*** harm ***against*** the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any. ***A significant risk of harm should be identified by assessing on the one hand the effect of such risk with respect to its level of severity, intensity, probability of occurrence and duration combined altogether and on the other hand whether the risk can affect an individual, a plurality of persons or a particular group of persons. Such combination could for instance result in a high severity but low probability to affect a natural person, or a high probability to affect a group of persons with a low intensity over a long period of time, depending on the context. Given the rapid pace of technological development, as well as the potential changes in the use of AI systems, the list of high-risk areas and use-cases in Annex III should nonetheless be subject to permanent review through the exercise of regular assessment (AM 519).***

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

(3) ~~'small-scale provider' means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC[7]~~ ***(AM. 937, 938***)

(4) '***deployer*** ~~user~~' ***(AM 944, 945, 946, 947)*** means any natural or legal person, public authority, agency or other body using an AI system under its authority ~~***and***~~, except where the AI system is used in the course of a ~~***its***~~ personal non-professional activity ***(AMs 56)***;

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(5) ‘authorised representative’ means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

~~***(5a) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark; (AM 954)***~~

(6) ‘importer’ means any natural or legal person established in the Union that places on the market or puts into service an AI system that bears the name or trademark of a natural or legal person established outside the Union;

(7) ‘distributor’ means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market without affecting its properties;

(8) ‘operator’ means the provider, ~~the user~~ ***the deployer (AM 958)***, the authorised representative, the importer and the distributor;

(8a) ‘affected person’ means any natural person or group of persons who are subject to or otherwise affected by an AI system; (AM 948, 951, 960, 961, 1116)

(9) ‘placing on the market’ means the first making available of an AI system on the Union market;

(10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(11) ‘putting into service’ means the supply of an AI system for first use directly to the ~~user~~ ***deployer (AM 963)*** or for own use on the Union market for its intended purpose;

(12) ‘intended purpose’ means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

(13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose ***as indicated in instructions for use established by the provider (AMs 973; 974; 975)***, but which may result from reasonably foreseeable human behaviour or interaction with other systems***, including other AI systems***; ***(AMs 976; 977; 978)***

(14) ‘safety component of a product or system’ means, ***in line with Union harmonisation legislation listed in Annex II, (AM 982)*** a component of a product or of a system which fulfils a ~~***direct***~~ ***critical (AM 982)*** safety function for that product or system~~, or~~ the failure or malfunctioning of which endangers the health and safety of persons~~, or property~~ ***(AM 982)*** ~~***or fundamental rights;***~~ ***(AMs 983, 984)***

(15) ‘instructions for use’ means the information provided***,*** ~~***on a durable medium (AM 58),***~~ by the provider to inform the ~~user~~ ***deployer (AM 989)*** of in particular an AI

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system's intended purpose and proper use, ***as well as information on any precautions to be taken (AM 58);*** inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

(16) 'recall of an AI system' means any measure aimed at achieving the return to the provider of an AI system ***that has been (AM 59)*** made available to ~~users~~ ***deployers (AM 992)***;

(17) 'withdrawal of an AI system' means any measure aimed at preventing the distribution, display and offer of an AI system;

(18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;

(19) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;

(20) 'conformity assessment' means the process of ~~verifying~~ ***demonstrating (AMs 998, 999)*** whether the requirements set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled;

(21) 'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection;

(22) 'notified body' means a conformity assessment body ~~designated~~ ***notified (AMs 60, 1000)*** in accordance with this Regulation and other relevant Union harmonisation legislation;

(23) 'substantial modification' means a ~~change~~ ***modification or a series of ~~changes~~ modifications (AM 61)*** ~~to~~ ***of*** the AI system ~~following~~ ***after*** its placing on the market or putting into service which ~~affects~~ ***is not foreseen or planned in the initial risk assessment by the provider and as a result of which (AMs 1002, 1007)*** the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation ***is affected*** or results in a modification to the intended purpose for which the AI system has been assessed ~~***or to its performance***~~; ~~***(AM 61)***~~

(24) 'CE marking of conformity' (CE marking) means a ***physical or digital*** marking by which a provider indicates that an ***AI system or a product with an embedded (AM 1009; 1010)*** AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products ('Union harmonisation legislation') providing for its affixing;

(25) 'post-market monitoring' means all activities carried out by providers of AI systems to proactively collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

(26) 'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020;

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(27) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;

(28) 'common specifications' means a document, other than a standard, containing technical solutions ~~***comprising a set of technical specifications (AM 1012)***~~ providing a means to, comply with certain requirements and obligations established under this Regulation;

(29) 'training data' means data used for training an AI system through fitting its learnable parameters, ~~including the weights of a neural network;~~ ***(AMs 1014; 1015)***

(30) 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent ***underfitting or (AMs 62, 1016)*** overfitting; whereas the validation dataset ~~can~~ ***is (AMs 1016, 1017, 1019)*** ~~be~~ a separate dataset or part of the training dataset, either as a fixed or variable split;

(31) 'testing data' means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;

(32) 'input data' means data provided to or directly acquired by an AI system on the basis of which the system produces an output;

(33) 'biometric data' means ***biometric data as defined in Article 4, point (14) of Regulation (EU) 2016/679;*** ~~personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data;~~ ***(AMs 63, 1022)***

(33a) 'biometrics-based data' means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person, ~~***such as facial expressions, movements, pulse frequency, voice, key strikes or gait, which may or may not allow or confirm the unique identification of a natural person;***~~ ***(AMs 64; 1025, 1026, 1027)***

(33b) 'biometric identification' means ~~***the use of AI systems for the purpose of***~~ ***the automated recognition of physical, physiological, behavioural, and psychological human features*** ~~***such as the face, eye movement, facial expressions, body shape, voice, speech, gait, posture, heart rate, blood pressure, odour, keystrokes, psychological reactions (anger, distress, grief, etc.)***~~ ***for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals in a database (one-to-many identification); (AM 1030 (S&D))***

(33c) '~~***remote***~~ ***biometric verification*** ~~***system***~~***' means*** ~~***an AI system for the purpose of verifying***~~ ***the automated verification of the identity of natural persons*** ~~***at a distance***~~ ***by comparing*** ~~***through the comparison of a person's***~~ ***biometric data of an individual to*** ~~***their***~~ ***previously provided biometric data (one-to-one verification)*** ~~***with the biometric data contained in a reference database with of the natural***~~

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~~***person, and with prior knowledge of the user of the AI system whether the person will be present and can be identified".***~~

~~***(33d) 'remote biometric authentication system' means an AI system for the purpose of authenticating the identity of natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database on request of the natural person".***~~

~~***(33b) 'subliminal techniques' means techniques that use sensorial stimuli such as images, text, or sounds, that go beyond the limits of conscious human sensorial perception; (AMs 65; 980; 1028; 1126***~~

(33d) 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU)2016/679; (AMs 66, 1029)

(34) 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions***, thoughts, states of mind*** or intentions of ~~natural persons~~ ***individuals or groups*** on the basis of their biometric ***and biometric-based*** data; ***(AMs 67, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1038)***

(35) 'biometric categorisation ~~system'~~ means ~~an AI system for the purpose of~~ assigning natural persons to specific categories, ***or inferring their characteristics and attributes (AMs 1043, 1044, 1045, 1046)***~~such as ***gender,*** sex, age, hair colour, eye colour, tattoos, ethnic ***or social*** origin***, health, mental or physical ability, behavioural or personality, traits language, religion, or membership of a national minority*** or sexual or political orientation~~, on the basis of their biometric ~~***and or***~~ ***biometric-based*** data, ***or which can be*** ~~***reasonably***~~ ***inferred from such data***; ***(AMs 68, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046)***

~~***(35 a) 'remote biometric categorisation system' means a biometric categorisation system capable of categorising natural persons at a distance; (AM 1047)***~~

(36) 'remote biometric identification system' means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge of the ~~user~~ ***deployer*** of the AI system whether the person will be present and can be identified***, excluding authentication and verification systems*** ~~***whose sole purpose is to confirm, based on prior consent, that a specific natural person is the person he or she claims to be or to confirm the identity of a natural person for the sole purpose of having access to a service, a device or premises***~~; ***(AMs 1049, 1050, 1051, 1052)***

~~***(36 a) 'at a distance' means the process of identification, verification or authentication in physical at a distance with indirect interaction with the data subject or without at a physical distance; (AM 1062)***~~

(37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also limited ~~short~~ delays in order to avoid circumvention.

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(38) ‘‘post’ remote biometric identification system’ means a remote biometric identification system other than a ‘real-time’ remote biometric identification system;

(39) ‘publicly accessible space’ means any ***publicly or privately owned*** physical place accessible to the public, regardless of whether certain conditions for access may apply***, and regardless of the potential capacity restrictions***; ***(AM 1068)***

(40) ‘law enforcement authority’ means:

(a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or

(b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(41) ‘law enforcement’ means activities carried out by law enforcement authorities ***or on their behalf (AM 1075)*** ~~***solely (AM 1076)***~~ for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(42) ‘national supervisory authority’ means ~~the~~ ***a public (AM 69)*** authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State ***in the management*** ~~at the European Artificial Intelligence~~ Board ***of the AI Office***; ***(AM 1078)***

(43) ‘national competent authority’ means ***any of*** the national ~~supervisory authority~~ ***authorities which are responsible for the enforcement of this Regulation*** ~~***other than the National Supervisory Authority***~~ ~~, the notifying authority and the market surveillance authority;~~

(44) ‘serious incident’ means any incident ***or malfunctioning of an AI system*** that directly or indirectly leads, might have led or might lead to any of the following:

(a) the death of a person or serious damage to a person’s health, ~~to property or the environment,~~

(b) a serious ~~and irreversible~~ disruption of the management and operation of critical infrastructure.

(ba) a breach of fundamental rights protected under Union law; (AMs 1082, 1087, 1090, 1094, 1095, 1097)

(c) serious damage to property or the environment

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(44a) 'personal data' means personal data as defined in Article 4, point (1) of Regulation (EU)2016/679; (AMs 71, 1121)

(44b) 'non-personal data' means data other than personal data; (AMs 72, 1123)

(44c) 'profiling' means any form of automated processing of personal data as defined in point (4) of Article 4 of Regulation (EU) 2016/679; (AM 1117) or in the case of law enforcement authorities – in point 4 of Article 3 of Directive (EU) 2016/680 or, in the case of Union institutions, bodies, offices or agencies, in point 5 Article 3 of Regulation (EU) 2018/1725; (3182, 3184)

(44d) 'deep fake' means manipulated or synthetic audio, image or video content that would falsely appear to be authentic or truthful, and which features depictions of persons appearing to say or do things they did not say or do, ~~without their consent~~, produced using AI techniques, including machine learning and deep learning; (AMs 1067; 1110, 1111, 1122)

(44e) 'widespread infringement' means:

(a) any act or omission contrary to Union law that protects the interests of individuals, that has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State, in which:

(i) the act or omission originated or took place;

(ii) the provider concerned, or, where applicable, its authorised representative is established; or,

(iii) the user is established, when the infringement is committed by the user;

(b) any acts or omissions contrary to Union law that protects the interests of individuals, that have done, do or are likely to do harm to the collective interests of individuals and that have common features, including the same unlawful practice, the same interest being infringed and that are occurring concurrently, committed by the same operator, in at least three Member States; (AM 74)

(44f) 'widespread infringement with a Union dimension' means a widespread infringement that has harmed or is likely to harm the collective interests of individuals in at least two-thirds of the Member States, accounting, together, for at least two-thirds of the population of the Union. (AM 75)

~~(44g) 'AI systems presenting a risk' means an AI system having the potential to affect adversely health and safety, fundamental rights of persons in general, including in the workplace, protection of consumers, the environment, public security, or the Union values enshrined in Article 2 TEU (AM 238, ENVI 100, TRAN 120) and other public interests, that are protected by the applicable Union harmonisation~~

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~~*legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the system are concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements (AM 1098)*~~

(44h) 'regulatory sandbox' means ~~a framework facility that provides~~ a controlled environment established by a public authority that facilitates the safe development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan under regulatory supervision; (AM 1099 (EPP), 1103 (RE))

(44i) 'critical infrastructure' means an asset, a facility, equipment, a network or a system, or a part of an asset, a facility, equipment, a network or a system, which is necessary for the provision of an essential service within the meaning of Article 2(4) of Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities; (AMs 1101, 1124)

(45a) 'lifecycle' means the entire ~~process duration of an AI system~~ period from the start of the development of an AI system to the moment when it is decommissioned;

(45b) 'lifetime' means the ~~period duration of an AI system~~ from the moment ~~that~~ when an AI system is placed on the market or put into service until the moment when it is decommissioned ~~no longer actively supported with patching and updates;~~

(45c) 'social scoring' means evaluating or classifying natural persons based on their social behaviour, socio-economic status or known or predicted personal or personality characteristics;

(45d) 'social behaviour' means the way a natural person interacts with and influences other natural persons or society;

(45e) 'state of the art' means the developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience;

(45f) 'testing in real world conditions' means the temporary testing of an AI system for its intended purpose in real world conditions outside of a laboratory or otherwise simulated environment;

~~*Article 4*~~

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~~*Amendments to Annex I*~~

~~The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.~~

~~ANNEX I~~
~~ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES referred to in Article 3, point 1~~

~~(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;~~

~~(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;~~

~~(c) Statistical approaches, Bayesian estimation, search and optimization methods.~~

Article 4a
General principles applicable to all AI systems

1. All operators falling under this Regulation shall make their best efforts to develop and use AI systems or foundation models in accordance with the following general principles establishing a high-level framework that promotes a coherent human-centric European approach to ethical and trustworthy Artificial Intelligence, which is fully in line with the Charter as well as the values on which the Union is founded:

• 'human agency and oversight' means that AI systems shall be developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be appropriately controlled and overseen by humans.

• 'technical robustness and safety' means that AI systems shall be developed and used in a way to minimize unintended and unexpected harm as well as being robust in case of unintended problems and being resilient against attempts to alter the use or performance of the AI system so as to allow unlawful use by malicious third parties.

• 'privacy and data governance' means that AI systems shall be developed and used in compliance with existing privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity.

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

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

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

2. Paragraph 1 is without prejudice to obligations set up by existing Union and national law. For high-risk AI systems, the general principles are translated into and complied with by providers or deployers by means of the requirements set out in Articles 8 to 15, and respective obligations laid down in Chapter 3 of Title III of this Regulation. For foundation models, the general principles are translated into and complied with by providers by means of the requirements set out in Articles 28 to 28b. For all other AI systems, the application of the principles referred to in paragraph 1 can be achieved, as applicable, through the provisions of Article 28, Article 52, or the application of harmonised standards, technical specifications, and codes of conduct as referred to in Article 69,without creating new obligations under this Regulation.

3. The Commission and the AI Office shall incorporate these guiding principles in standardisation requests as well as recommendations consisting in technical guidance to assist providers and deployers on how to develop and use AI systems. European Standardisation Organisations shall take the general principles referred to in paragraph 1 into account as outcome-based objectives when developing the appropriate harmonised standards for high risk AI systems as referred to in Article 40(2b).

Possible new Article 4b on right to explanation

Could cover: AM 1149 (ECR), 1151 (S&D), 1152 (Greens), 1153 (S&D), 2391 (TheLeft), JURI 150

Article 4b

A right to explanation of individual decision-making

1. Any affected person subject to a decision which is taken by the ~~provider or user~~ deployer on the basis of the output from an high-risk AI system ~~falling within the scope of this Regulation and~~ which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely i impact their health, safety, fundamental rights, socio-economic well-being or any other of the rights deriving from the obligations laid down in this Regulation, ~~on an affected person, or which similarly significantly affects that person~~ shall have the right to request

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from the deployer clear and meaningful explanation pursuant to Article 13(1) on the role of the AI system in the decision-making procedure, the main parameters of the decision taken and the related input data. ~~*receive from the provider or the deployer, at the time when the decision is communicated, a clear and meaningful explanation pursuant to Article 13(1) on of the role of the AI system in the decision-making procedure, the main parameters of the decision taken and the related input data. be accompanied by a meaningful explanation of:*~~

~~*(a) the role of the AI system in the decision-making process;*~~

~~*(b) the logic involved, the main parameters of the decision-making, and their relative weight; and*~~

~~*(c) the input data relating to the affected person and each of the main parameters on the basis of which the decision was made.*~~

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

~~*2. For the purpose of Paragraph 1, it shall be prohibited for the law enforcement authorities or the judiciary in the Union to use AI systems that are considered closed or labelled as proprietary by the providers or the distributors;*~~

2. Paragraph 1 shall not apply to the use of AI systems:for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law are provided in so far as such exception or restrictions respect the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society.

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

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

3. This Article shall apply without prejudice to Articles 14, 15, and 22 of the Regulation 2016/679

Obtenu par CONTEXTE

Possible new Article 4c on accessibility:
Could cover: AM 1148 (S&D), 1403 (TheLeft), 1407 (TheLeft)

Obtenu par CONTEXTE

Article 4d
AI literacy

1. *When implementing this Regulation, the Union and the Member States shall promote measures for the development of a sufficient level of AI literacy, across sectors and taking into account the different needs of groups of providers, deployers and affected persons concerned, including through education and training, skilling and reskilling programmes and while ensuring proper gender and age balance, in view of allowing a democratic control of AI systems.*
2. *Providers and deployers of AI systems shall take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on which the AI systems are to be used.*
3. *Such literacy measures shall consist, in particular, of the teaching of basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits.*
4. *A sufficient level of AI literacy is one that contributes, as necessary, to the ability of providers and deployers to ensure compliance and enforcement of this Regulation.*

Matching definition:

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

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

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COMPROMISE AMENDMENTS BATCH 11; VERSION 4 17/02/2023

Covers: 76 (Rapp.), 77 (Rapp.), 1157 (S&D), 1158 (Greens), 1159 (Left), 1160 (S&D), 1162 (Left), 1163 (RE), 1166 (EPP), 1167 (EPP), 1169 (RE), 1172 (RE), 1174 (Greens), 1175 (Left), 1176 (S&D), 1177 (S&D), 1178 (ECR), 1179 (ID), 1180 (RE), 1181 (RE), 1182 (S&D), 1184 (EPP), 1187 (Left), 1188 (ID), 1189 (ECR), 1191 (S&D), 1192 (S&D), 1193 (Left), 1194 (RE), 1195 (Greens), 1196 (ECR), 1197 (RE), 1207 (ECR), 1208 (RE), 1209 (EPP), 1218 (ECR), 1219 (EPP), 1220 (RE), 1222 (S&D), 1223 (RE), 1226 (ID), 1232 (The Left), 1233 (RE), 1234 (RE), 1235 (RE), 1236 (ECR), 1237 (S&D), 1238 (The Left), 1239 (MEPs), 1242 (Greens), 1244 (S&D), 1245 (ECR), 1246 (S&D), 1247 (The Left), 1248 (Greens), 1249 (The Left), 1250 (MEPs), 1251 (ECR), 1252 (S&D), 1253 (RE), 1254 (RE), 1256 (ECR), 1257 (S&D), 1258 (The Left), 1259 (Greens), 1260 (RE), 1261 (MEPs), 1262 (ECR), 1263 (RE), 1264 (The Left), 1265 (S&D), 1268 (ECR), 1269 (MEPs), 1270 (ECR), 1271 (ECR), 1272 (S&D), 1273 (RE), 1274 (RE), 1275 (ECR), 1276 (The Left), 1277 (S&D), 1278 (The Left), 1279 (Greens), 1285 (Left), 1290 (MEPs), 1302 (Left), 1307 (S&D), 1312 (Left), 1331 (Left), 1338 (Left), 1348 (RE), 1349 (Greens), 1350 (S&D), 1351 (S&D), 1352 (ECR), 1353 (MEPs), 1354 (RE), 1355 (EPP), 1356 (RE), 1357 (RE), 1358 (RE), 1359 (RE), 1361 (RE), 1362 (RE), 1364 (RE), 1365 (EPP), 1366 (Greens), 1367 (RE), 1368 (S&D), 1369 (ECR), 1370 (S&D), 1371 (MEPs), 1375 (RE), 1376 (RE), 1377 (Greens), 1289 (Greens), 1298 (S&D), 1300 (S&D), 1305 (ECR), 1326, 1327, 1339 (Left), 1380 (S&D), 1381 (RE), 1382 (S&D), 1383 (EPP), 1384 (MEPs), 1385 (ECR), 1386 (S&D), 1387 (RE), 1388 (Greens), 1394 (S&D),

Falls: 1155 (Greens), 1156 (Greens), 1159 (Left), 1161 (ID), , 1164 (RE), 1165 (EPP), 1168 (ECR), 1170 (S&D), 1171 (EPP), 1173 (S&D), 1183 (EPP), 1185 (RE), 1186 (EPP), 1190 (ECR), 1198 (ID), 1199 (ECR), 1200 (Left), 1201 (S&D), 1202 (S&D), 1203 (Greens), 1204 (RE), 1205 (Left), 1206 (ECR), 1210 (ID), 1211 (ECR), 1212 (S&D), 1213 (RE), 1214 (Greens), 1215 (Left), 1216 (Left), 1217 (S&D), 1221 (ECR), 1224 (ID), 1227 (ID), 1228 (ID), 1229 (ID), 1230 (EPP), 1231 (ID), 1240 (EPP), 1241 (ECR), 1243 (EPP), 1255 (ECR), 1266 (EPP), 1267 (ID), 1280 (EPP), 1281 (ID), 1282 (ECR), 1283 (Left), 1284 (S&D), 1286 (RE), 1287 (RE), 1288 (S&D), 1291 (ECR), 1292 (MEPs), 1296 (RE), 1299 (RE), 1301 (Left), 1303 (MEPs), 1304 (Greens), 1306 (Greens), 1308 (MEPs), 1309 (Left), 1310 (Left), 1313 (RE), 1314 (Left), 1315 (Greens), 1316 (S&D), 1318 (Greens), 1319 (S&D), 1320 (Left), 1322 (S&D), 1323 (Greens), 1324 (Left), 1325 (RE), 1328 (S&D), 1329 (Greens), 1330 (Left), 1332 (S&D), 1333 (Left), 1334 (Greens), 1335 (Left), 1336 (Greens), 1340 (Greens), 1341 (Left), 1342 (Greens), 1343 (Greens), 1344 (Greens), 1345 (Greens), 1346 (Greens), 1360 (ECR), 1363 (ECR), 1372 (ECR), 1373 (EPP), 1374 (Left), 1378 (ID), 1379 (ECR), 1389 (ECR), 1390 (ECR), 1391 (EPP), 1392 (Left), 1393 (Left), 1396 (S&D), 1397 (Left), 1398 (S&D), 1399 (S&D), 1400 (S&D), 1401 (S&D), 1402 (S&D), 1404 (Left), 1405 (MEPs), 1406 (Left)

Orgi Do Not Circulate

Parked: 1403, 1407 (Left) - accessibility requirements, 1345 (Greens) - no EU funding of research, 1225 (S&D), 1293 (Left), 1294 (Left), 1295 (Greens), 1297 (ECR), 1321, 1337 (Left), 1347, 1395 (S&D) - emotion recognition, 1311 (RE), 1317 (RE),

Article 5

1. The following artificial intelligence practices shall be prohibited:

(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness ***or purposefully manipulative (AM 1162) or deceptive (AM 1159) techniques, with the objective to or the effect of (AM 1157, 1166, 1169)*** materially distort***ing*** a person's ***or a group of persons (AM 1158)*** behaviour ***by appreciably impairing the person's ability to make an informed decision, thereby causing the person to take a decision they would not have taken otherwise (AM 1157, 1158,*** 1160) in a manner that causes or is likely to cause that person***,*** another person ***or group of persons significant ~~physical or psychological~~ (AM 1166)*** harm;

The prohibition of AI system that deploys subliminal techniques referred to in the first sub-paragraph shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of ~~explicit~~ specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian (AM 1163)

(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a ***person or a specific group of persons, including characteristics of such individual's or group of persons' known or predicted personality traits or social or economic situation (AM 1174, 1175, 1176, 1178, 1179, 1180, 1181, 1182)***, age, physical or mental ability ***(AM 1176, 1177)***, ***with the objective or to the effect of (AM 1184)*** materially distort***ing*** the behaviour of ***that person or*** a person pertaining to that group in a manner that causes or is likely to cause that person or another person ***significant ~~physical or psychological~~*** harm**;**

(ba) the placing on the market, putting into service or use of biometric categorisation systems that categorise natural persons according to sensitive or protected attributes or characteristics or based on the inference of those attributes or characteristics . (AMs 1289, 1298, 1300, 1305, 1326, 1327, 1339, 1347, 1380). This prohibition shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.

(c) the placing on the market, putting into service or use of AI systems ~~by public authorities or on their behalf~~ (***AM 1187, 1188, 1189, 1191, 1192, 1193 1194, 1195, 1196)*** for the ***social scoring (AM 1191, 1194, 1196, 1197),*** evaluation or classification of ~~the trustworthiness of~~ (***AM 1187, 1191, 1194, 1196, 1197)*** natural persons ***or groups thereof (AM 1191, 1193, 1195, 1196)*** over a certain period of time based on their social behaviour or known***, inferred (1195)*** or predicted personal

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or personality characteristics, with the social score leading to either or both of the following:

(i) ~~***preferential (AM 1207, 1220),***~~ detrimental or unfavourable treatment of certain natural persons or **(*AM 1209*)** groups thereof in social contexts ***that (AM 1208)*** are unrelated to the contexts in which the data was originally generated or collected;

(ii) ~~***preferential (AM 1218),***~~ detrimental or unfavourable treatment of certain natural persons or ***(AM 1219)*** groups thereof that unjustified or disproportionate to their social behaviour or its gravity;

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

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

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

~~(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA62 and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State.~~ ***(AMs 1232 (The Left), 1233 (RE), 1234 (RE), 1235 (RE), 1236 (ECR), 1237 (S&D), 1238 (The Left), 1239 (MEPs), 1242 (Greens), 1244 (S&D), 1245 (ECR), 1246 (S&D), 1247 (The Left), 1248 (Greens), 1249 (The Left), 1250 (MEPs), 1251 (ECR), 1252 (S&D), 1253 (RE), 1254 (RE), 1256 (ECR), 1257 (S&D), 1258 (The Left), 1259 (Greens), 1260 (RE), 1261 (MEPs), 1262 (ECR), 1263 (RE), 1264 (The Left), 1265 (S&D), 1268 (ECR), 1269 (MEPs), 1270 (ECR), 1271 (ECR), 1272 (S&D), 1273 (RE), 1274 (RE), 1275 (ECR), 1276 (The Left), 1277 (S&D), 1278 (The Left), 1279 (Greens))***

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

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

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

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

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~~geographic and personal limitations~~. ***(AMs 1348 (RE), 1349 (Greens), 1350 (S&D), 1351 (S&D), 1352 (ECR), 1353 (MEPs), 1354 (RE), 1355 (EPP), 1356 (RE), 1357 (RE), 1358 (RE), 1359 (RE), 1361 (RE), 1362 (RE))***

~~3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use. The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2.~~ ***(AMs 1364 (RE), 1365 (EPP), 1366 (Greens), 1367 (RE), 1368 (S&D), 1369 (ECR), 1370 (S&D), 1371 (MEPs), 1375 (RE), 1376 (RE), 1377 (Greens))***

~~4. A Member State may decide to provide for the possibility to fully or partially authorise the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be authorised to use those systems for the purpose of law enforcement.~~ ***(AMs 1381 (RE), 1382 (S&D), 1383 (EPP), 1384 (MEPs), 1385 (ECR), 1386 (S&D), 1387 (RE), 1388 (Greens))***

(da) the placing on the market, putting into service or use of an AI system for making ~~individual~~ risk assessments of natural persons or groups thereof in order to assess the risk of a natural person for offending or reoffending or for predicting the occurrence or reoccurrence of an actual or potential criminal or administrative offence based on profiling of a natural person or on assessing personality traits and characteristics, including the person's location, or past criminal behaviour of natural persons or groups of natural persons;

(db) The placing on the market, putting into service or use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage; (AMs 1287, 1288, 1309, 1333, 1336)

(dc) the placing on the market, putting into service or use of AI systems to infer emotions of a natural person in the areas of law enforcement, border management, in workplace and education institutions. ~~This prohibition shall not apply to AI~~

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~~*system inferring emotions of a natural person for health or research purposes provided the data subject has given consent to the processing of data concerning him or her pursuant to Articles 7 to 9 in the GDPR.*~~

(e) the ~~placing on the market,~~ putting into service or use of AI systems for the analysis of recorded footage of publicly accessible spaces through 'post' remote biometric identification systems, ~~unless and in as far as such use is pre-approved by a judge~~ subject to a pre-judicial authorisation in accordance with Union law and strictly necessary for the targeted search connected to a specific serious criminal offense as defined in Article 83(1) of TFEU that already took place for the purpose of law enforcement.

1a. This Article shall not affect the prohibitions that apply where an artificial intelligence practice infringes another EU law, including EU acquis on data

RECITALS

Covers: AMs 14 (Rapp.), 15 (Rapp.), 16 (Rapp.), 17 (Rapp.), 414 (S&D), 415 (Greens), 424 (EPP), 425 (Greens), 427 (S&D), 428 (RE), 429 (S&D), 430 (RE), 432 (ID), 433 (S&D), 434 (RE), 435 (Greens), 436 (S&D), 437 (Left), 440 (S&D), 441 (MEPs), 442 (S&D), 443 (RE), 447 (S&D), 448 (S&D), 449 (Greens), 450 (RE), 451 (RE), 452 (Left), 454 (MEPs), 455 (ID), 461 (Left), 462 (EPP), 463 (S&D), 464 (RE), 465 (MEPs), 466 (S&D), 467 (RE), 469 (Left), 472 (S&D), 473 (RE), 474 (MEPs), 475 (S&D), 476 (Greens), 477 (RE), 478 (EPP), 481 (S&D), 482 (S&D), 483 (RE), 484 (Greens), 485 (Left), 486 (RE), 487 (MEPs), 490 (RE), 491 (S&D), 492 (Greens), 493 (S&D), 494 (RE), 495 (MEPs), 497 (RE), 498 (MEPs), 499 (RE), 500 (S&D), 501 (S&D), 510 (S&D), 511 (RE), 512 (RE), 513 (Greens), 516 (S&D), 517 (S&D),

Falls: 416 (ID), 426 (ID), 431 (EPP), 438 (Greens), 439 (EPP), 444 (Greens), 445 (Greens), 446 (EPP), 453 (Left), 456 (S&D), 457 (Left), 458 (Left), 459 (Greens), 460 (S&D), 468 (ECR), 471 (ID), 479 (Left), 480 (Left), 488 (Left), 489 (EPP), 496 (EPP), 502 (Greens), 503 (Left), 504 (Left), 505 (ID), 506 (EPP), 509 (S&D), 514 (Left), 515 (RE), 518 (S&D),

Parked: 417 (EPP), 418, 419 (Left), 420 (Greens), 421 (S&D), 422 (Left), 423 (Greens) - Accessibility

(14) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain ***unacceptable (AMs 14, 414)*** artificial intelligence practices, to lay down requirements for high-risk AI

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systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.

(15) Aside from the many beneficial uses of artificial intelligence, that technology can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful ***and abusive (AM 15)*** and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child.

(16) The placing on the market, putting into service or use of certain AI systems ***with the objective to or the effect of*** ~~intended to~~ ***materially*** distort***ing (AMs 424, 430)*** human behaviour, whereby physical or psychological harms are likely to occur, should be forbidden. ***This limitation should be understood to include neuro-technologies assisted by AI systems that are used to monitor, use, or influence neural data gathered through brain-computer interfaces insofar as they are materially distorting the behaviour of a natural person in a manner that causes or is likely to cause that person or another person significant harm(AM 427, 429)***. Such AI systems deploy subliminal components individuals cannot perceive or exploit vulnerabilities of ***individuals (AM 425)*** ~~children~~ and ***specific groups of persons (AM 424)*** ~~people~~ due to their ***known or predicted personality traits,*** age, physical or mental incapacities***, social or economic situation (AM 4230)***. They do so with the intention to ***or the effect of*** materially distort***ing*** the behaviour of a person and in a manner that causes or is likely to cause ***significant*** harm to that or another person ***or groups of persons, including harms that may be accumulated over time (AM 424)***. The intention ***to distort the behaviour*** may not be presumed if the distortion ~~of human behaviour~~ results from factors external to the AI system which are outside of the control of the provider or the user***, such as factors that may not be reasonably foreseen and mitigated by the provider or the deployer of the AI system (AM 424)***. ***In any case, it is not necessary for the provider or the deployer to have the intention to cause the significant harm, as long as such harm results from the manipulative or exploitative AI-enabled practices. The prohibitions for such AI practices is complementary to the provisions contained in Directive [Unfair Commercial Practice Directive 2005/29/EC, as amended by Directive (EU) 2019/216], ~~notably that~~ according to which unfair commercial practices ~~leading to economic or financial harms to consumers~~ are prohibited ~~under all circumstances~~, irrespective of whether they are carried out ~~put in place through~~ having recourse to AI systems or otherwise (AM 424)***. ***In such setting, lawful ~~Legitimate~~ commercial practices, for example in the field of advertising, that are in compliance with Union law should not in themselves be regarded as violating ~~the~~ prohibition inasmuch as they are carried out without having recourse to any of the AI systems, the placing on the market, putting into service or use of which is prohibited pursuant to this regulation***. Research for legitimate purposes in relation to such AI systems should not be stifled by the prohibition, if such research does not amount to use of the AI system in human-machine relations that exposes natural persons to harm and such research is carried out in accordance with recognised ethical standards for scientific research ***and***

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on the basis of ~~explicit~~ specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.

(16a) AI systems that categorise natural persons by assigning them to specific categories, according to known or inferred sensitive or protected characteristics are particularly intrusive, violate human dignity and hold great risk of discrimination. Such characteristics include gender, gender identity, race, ethnic origin, migration or citizenship status, political orientation, sexual orientation, religion, disability or any other grounds on which discrimination is prohibited under Article 21 of the EU Charter of Fundamental Rights, as well as under Article 9 of Regulation (EU)2016/769. Such systems should therefore be prohibited (AMs 461, 507).

(17) AI systems providing social scoring of natural persons for general purpose ~~by public authorities or on their behalf~~ ***(AM 432, 433, 435, 436)*** may lead to discriminatory outcomes and the exclusion of certain groups. They ~~may~~ (***AM 437)*** violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify ~~the trustworthiness of~~ (***AM 434, 437)*** natural persons ***or groups*** based on ***multiple data points and time occurrences related to (AM 435)*** their social behaviour in multiple contexts or known***, inferred (AM 435)*** or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited.

(18) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces ~~for the purpose of law enforcement~~ ***(AMs 448, 449, 450, 451, 454)*** is ~~considered~~ ***(AM 448)*** particularly intrusive ***to~~in~~*** the rights and freedoms of the concerned persons, ***and can ultimately (AM 449)*** ~~to the extent that it may~~ affect the private life of a large part of the population, evoke a feeling of constant surveillance***, give parties deploying biometric identification in publicly accessible spaces a position of uncontrollable power (AM 449)*** and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights ***at the core to the Rule of Law (AM 449)***. ***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 (AM 447).*** In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in 'real-time' carry heightened risks for the rights and freedoms of the persons that are concerned by law enforcement activities. ***The use of those systems in publicly accessible places should therefore be prohibited (AMs 450, 451, 470).***

~~(19) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in three exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for potential victims of~~

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~~crime, including missing children; certain threats to the life or physical safety of natural persons or of a terrorist attack; and the detection, localisation, identification or prosecution of perpetrators or suspects of the criminal offences referred to in Council Framework Decision 2002/584/JHA[8] if those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years and as they are defined in the law of that Member State. Such threshold for the custodial sentence or detention order in accordance with national law contributes to ensure that the offence should be serious enough to potentially justify the use of 'real-time' remote biometric identification systems. Moreover, of the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA, some are in practice likely to be more relevant than others, in that the recourse to 'real-time' remote biometric identification will foreseeably be necessary and proportionate to highly varying degrees for the practical pursuit of the detection, localisation, identification or prosecution of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences.~~ (***AMs 462, 463, 464, 465, 466, 467)***

(20) ~~In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those three exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should be subject to appropriate limits in time and space, having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The reference database of persons should be appropriate for each use case in each of the three situations mentioned above.~~ ***(AMs 472, 473, 474, 475, 476, 477, 478)***

(21) ~~Each use of a 'real-time' remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State. Such authorisation should in principle be obtained prior to the use, except in duly justified situations of urgency, that is, situations where the need to use the systems in question is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use. In such situations of urgency, the use should be restricted to the absolute minimum necessary and be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations seek to obtain an authorisation as soon as possible, whilst providing the reasons for not having been able to request it earlier.~~ ***(AMs 481, 482, 483, 484, 485, 486, 487)***

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

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~~(22) Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State in question has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation.~~ ***(AMs 490, 491, 492, 493, 494, 495)***

~~(23) The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as *lex specialis* in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should only be possible in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In this context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive 2016/680. However, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to it.~~ ***(AM 497, 498, 499, 500, 501)***

(24) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of 'real-time' remote biometric identification systems in publicly accessible spaces ~~for the purpose of law enforcement~~ as regulated by this Regulation, ~~including where those systems are used by competent authorities in publicly accessible spaces for other purposes than law enforcement~~, ***(AMs 510, 511, 512, 513)*** should continue to comply with all requirements resulting from Article 9(1) of Regulation (EU) 2016/679, Article 10(1) of Regulation (EU) 2018/1725 and Article 10 of Directive (EU) 2016/680, as applicable.

(25) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in Article 5(1), point (d), ~~(2) and (3)~~ ***(AM 516)*** of this Regulation adopted on the basis of Article 16 of the TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police

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cooperation which require compliance with the provisions laid down on the basis of Article 16 of the TFEU.

(26) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and TFEU, Denmark is not bound by rules laid down in Article 5(1), point (d), ~~(2) and (3)~~ ***(AM 517)*** of this Regulation adopted on the basis of Article 16 of the TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.

(26a) AI systems used by law enforcement authorities or on their behalf to make predictions, profiles or risk assessments based on data analysis or profiling of natural persons, groups or locations, for the purpose of predicting the occurrence or reoccurrence of an actual or potential criminal offence(s) or other criminalised social behaviour, hold a particular risk of discrimination against certain persons or groups of persons, as they violate human dignity as well as the key legal principle of presumption of innocence. Such AI systems should therefore be prohibited. (AMs 16, 440, 441, 442, 443).

(26b) The indiscriminate and untargeted scraping of biometric data from social media or CCTV footage to create or expand facial recognition databases add to the feeling of mass surveillance and can lead to gross violations of fundamental rights, including the right to privacy. The use of AI systems with this intended purpose should therefore be prohibited.

(26c) Practices that are prohibited by Union legislation, including data protection law, non-discrimination law, consumer protection law, and competition law, should not be affected by this Regulation (AMs 17, 415).

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AI ACT - COMPROMISE AMENDEMENTS - BATCH 10 - V3. 16/02/2023

CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK

COMP AM 11a

Covering: 78 (Rapp), 79 (Rapp), 80 (Rapp), 81 (Rapp), 82 (Rapp), 83 (Rapp), 84 (Rapp), 85 (Rapp), 86 (Rapp), 87 (Rapp), 88 (Rapp), 1421 (Left), 1423 (RE), 1430 (Left), 1433 (S&D), 1435 (RE), 1436 (EPP), 1438 (EPP), 1439 (EPP), 1440 (EPP), 1441 (ECR), 1462 (S&D), 1498 (ECR), 1468 (RE), 1469 (Left), 1476 (RE), 1478 (Left), 1479 (S&D), 1480 (Greens), 1481 (S&D), 1472 (Left), 1473 (S&D), 1474 (Greens), 1475 (S&D), 1461 (Left), 1463 (S&D), 1464 (Greens), 1465 (ID), 1466 (RE), 1467 (EPP), 1468 (RE), 1469 (S&D), 1471 (ID), 1472 (The Left), 1473 (ID), 1474 (Greens), 1475 (S&D), 1476 (RE), 1477 (ID), 1478 (The Left), 1479 (S&D), 1480 (Greens), 1481 (S&D), 1482 (Left), 1483 (ECR), 1487 (ID), 1488 (S&D), 1489 (Greens), 1490 (The Left), 1492 (ECR), 1497 (EPP), 1499 (S&D), 1500 (ECR), 1501 (EPP), 1502 (S&D), 1503 (RE), 1506 (S&D), 1507 (S&D), 1508 (Greens), 1509 (ECR), 1510 (Left), 1520 (RE), 1521 (EPP), 1545 (Left), 1523 (Greens), 1513 (Left),

1519 (Greens), 1525 (S&D), 1526 (S&D), 1527 (Greens), 1528 (Left), 1529 (EPP), 1530 (EPP), 1531 (RE), 1532 (EPP), 1533 (EPP), 1534 (EPP), 1535 (EPP), 1536 (EPP), 1538 (RE), 1539 (EPP), 1542 (Greens), 1543 (Left), 1544 (Left), 1545 (Left), 1546 (ID),1449 (Greens),1466 (RE), 1467 (EPP), 1547 (S&D), 1548 (EPP), 1550 (EPP), 89 (Rapp), 1551 (ID), 1552 (ID),

Fall: 1408 (EPP), 1409 (EPP), 1410 (Greens), 1411 (EPP), 1412 (EPP), 1413 (S&D), 1414 (EPP), 1415 (Greens), 1416 (Left), 1417 (EPP), 1418 (Greens), 1419 (ID), 1422 (EPP), 1425 (Greens), 1426 (Greens), 1427 (Greens), 1428 (EPP), 1429 (RE), 1431 (ECR), 1432 (Left), 1437 (RE), 1442 (EPP), 1443 (EPP), 1444 (ECR), 1445 (EPP), 1446 (Greens), 1448 (Left), 1450 (Left), 1456 (RE), 1457 (Greens), 1459 (EPP), 1460 (EPP), 1470 (Left), 1484 (EPP), 1486 (EPP), 1487 (ID), 1491 (RE), 1493 (ID), 1498 (ID), 1505 (ID), 1512 (ID), 1514 (Greens), 1515 (ID), 1516 (EPP), 1517 (Left), 1518 (Greens), 1541 (Left), 1549 (RE), 1522 (ID), 1524 (ID), 1537 (ID), 1540 (Left), 1541 (Left)

Parked for later: 1420 (RE) foreseeable uses; 1424 (Greens) GPAI; 1434 (Left) FRIA; 1774 (S&D) GPAI; 1452 (S&D) foreseeable uses; 1453 (Left) Annex III; 1454 (Left) Annex III; 1455 (Left) GPAI; 1458 (RE) governance; 1485 (Left) Annex III; 1494 (Left) reasonably foreseeable uses; 1495 (Greens) reasonably foreseeable misuses; 1496 (RE) reasonably foreseeable; ; 1504 (S&D), 1511 (Greens) Annex III; 1447 (S&D) - indeterminate uses

TITLE III

HIGH-RISK AI SYSTEMS

CHAPTER 1

CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK

Article 6
Classification rules for high-risk AI systems

1. Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:

   (a) the AI system is intended to be used as a safety component of a product, or ***the AI system*** is itself a product, covered by the Union harmonisation legislation listed in Annex II~~***, the failure or malfunctioning of which endangers the health, safety, or fundamental rights of natural persons (AM 1421, 1431)***~~;

   b) the product whose safety component ~~***as meant under***~~ ***pursuant to point (a) (AM 1429, 1430)*** is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment ***related to risks for health and safety~~fundamental rights~~*** with a view to the placing on the market

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or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

Version 1

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems ***~~with an intended purpose (AM 1436)~~ falling under one or more of the critical areas and use cases*** referred to in Annex III shall be considered high-risk ***if they pose a significant risk of harm to the health, safety or fundamental rights of natural persons. and, where an AI system falls under Annex III point 2, the environment. ~~in a way that produces legal effects concerning them or has an equivalently significant effect on them~~ (AM ~~1435~~, 1436, 1438, 1439, 1440, 1441)***.

Version 2

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems ***~~with an intended purpose (AM 1436)~~ falling under one or more of the critical areas and use cases*** referred to in Annex III shall be considered high-risk ***if they pose a significant risk of harm to the health, safety or fundamental rights of natural persons. Where an AI system falls under Annex III point 2, it shall be considered high-risk if it poses a significant risk of harm to the environment. ~~in a way that produces legal effects concerning them or has an equivalently significant effect on them~~ (AM ~~1435~~, 1436, 1438, 1439, 1440, 1441)***.

~~In order to ensure uniform conditions for the implementation of this Regulation,~~ The Commission shall, 6 months prior to the entry into force of this Regulation, following consultation with the AI Office and relevant stakeholders, provide guidelines clearly specifying the circumstances where the output of AI systems referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons or cases in which it would not.

3. Where providers falling under one or more of the critical areas and use cases referred to in Annex III consider that their AI system does not pose a significant risk as described in paragraph 2, they shall submit a reasoned notification ~~to~~ the National Supervisory Authority ~~for an exemption from fulfilling~~ that they are not subject to the requirements of Title III Chapter 2 of this Regulation. ~~Upon receiving this request, the National Supervisory Authority shall enter into regulatory dialogue with the provider and provide a reasoned decision within 1 month~~. Where the AI system is intended to be used in two or more Member States, the aforementioned ~~application~~ notification shall be addressed to the AI Office ~~and its decision(s) shall be considered as part of its coordinating pursuant to Article 56f.~~ Without prejudice to Article 65, the National Supervisory Authority~~may raise an objection~~ shall review and reply, directly or via the AI Office, within 3 months if they deem the AI system to be misclassified. ~~shall issue their~~

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~~decision on the notification within 3 months from the day of receipt of the notification~~.

4. Providers that misclassify their AI system as not subject to the requirements of Title III Chapter 2 of this Regulation and place it on the market before the deadline for objection by National Supervisory Authorities shall be responsible and be subject to fines pursuant to Article 71.

5. National supervisory authorities shall submit a yearly report to the AI Office detailing the number of notifications received, the related high-risk areas at stake and the ~~number of~~ decisions taken concerning received notifications.

Covered: AMs 981 (EPP), 982 (EPP), 983 (S&D), 984 (S&D), 985 (The Left), 986 (EPP)
Falls

'safety component of a product or system' means, ***in line with Union harmonisation legislation listed in Annex II, (AM 982)*** a component of a product or of a system which fulfils a ***~~direct~~ critical (AM 982)*** safety function for that product or system***~~, or~~*** the failure or malfunctioning of which endangers the health and safety of persons***~~, or property~~ (AM 982) ~~or~~ ~~fundamental rights;~~(AMs 983, 984)***

Article 7
Amendments to Annex III

1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to ~~update the list in~~ ***amend*** Annex III ***~~including~~*** ~~by~~ ***~~removing or by~~ (AM 1449, 1466, ~~1548)~~ by*** ~~adding~~ ***or modifying areas or use-cases of (AM 1468, 1476)*** high-risk AI systems where ~~both of the following conditions are fulfilled:~~

~~(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;~~ ***(AMs 78, 1469, 1472, 1473, 1474, 1475)***

~~(b) the AI systems~~ ***(AM 1478, 1479, 1480, 1481)*** ~~–~~ ***these*** pose a ***significant (AM 1484)*** risk of harm to ~~the~~ health and safety, ~~or a risk o~~***r an*** adverse impact on fundamental rights, ***to the environment, or to democracy and the rule of law (AM 1462, 1492),*** ~~that is~~ ***and that risk is,*** in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. ***(AMs 79, 80, 1461, 1463, 1464, 1465, 1482, 1483)***

1a. The Commission is also empowered to adopt delegated acts in accordance with Article 73 to remove use-cases of high-risk AI systems from the list in Annex III if the conditions referred to in paragraph 1 no longer apply (AM 1548)

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2. When assessing ***an AI system*** for the purposes of paragraph 1 ***and 1a*** ~~whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III~~ ***(AM 81, 1487, 1488, 1489)***, the Commission shall take into account the following criteria:

(a) the intended purpose of the AI system;

(aa) the general capabilities and functionalities of the AI system independent of its intended purpose; (AM 1497, 1543)

(b) the extent to which an AI system has been used or is likely to be used ***~~and misused~~ (AMs 1499, 1500)***;

(ba) the ~~type,~~ nature and amount of the data processed and used by the AI system; (AM 83, 1502, 1535)

(bb) the extent to which the AI system acts autonomously; (AM 1501, 1503)

(c) the extent to which the use of an AI system has already caused harm to ***~~natural persons~~,*** ~~the~~ health ***and*** safety ~~or~~***, has had an*** adverse impact on ~~the~~ fundamental rights, ***the environment, democracy and the rule of law (AMs 84, 1490, 1508, 1509, 1510)*** or has given rise to significant concerns in relation to the ***~~materialisation~~ likelihood*** of such harm or adverse impact, as demonstrated ***for example*** by reports or documented allegations submitted to national ~~competent~~ ***supervisory*** authorities***, to the Commission, to the AI Office, to the EDPS, or to the European Union Agency for Fundamental Rights (AM 84, 1506, 1507)***;

(d) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons ***or to disproportionately affect a particular group of persons (AM 85, 1513)***;

(e) the extent to which potentially harmed or adversely impacted persons are dependent on the ***~~outcome~~ output*** produced ***~~with~~ involving (AM 1518)*** an AI system, ***and that output is purely accessory in respect of the relevant action or decision to be taken***, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that ***~~outcome~~ output***; ***(AM 1516, 1519)***

(ea) the potential misuse and malicious use of the AI system and of the technology underpinning it; (AMs 82, 1520, 1521, 1545)

(f) the extent to which ***there is an imbalance of power, or the*** potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due ***~~to an imbalance of power~~, status, authority, (AM 1523)*** knowledge, economic or social circumstances, or age;

(g) the extent to which the outcome produced ***~~with~~ involving*** an AI system is easily reversible ***or remedied (AM 1529)***, whereby outcomes having an ***adverse*** impact on the health~~, or~~ safety***, fundamental rights*** of persons***, the environment, or on democracy and rule of law*** shall not be considered as easily reversible; ***(AM 86, 1525, 1526, 1527, 1528)***

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(ga) the extent of the availability and use of effectivetechnical solutions and mechanisms for the control, reliability and corrigibility of the AI system; (AM 1530, 1544)

(gaa) magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety ; (AM 1531, 1533, 1534, 1536)

(gb) the extent of human oversight and the possibility for a human to intercede in order to override a decision or recommendations that may lead to potential harm; (AM 1532)

(h) the extent to which existing Union legislation***, ~~in particular the GDPR~~, (AM 1538, 1539)*** provides for:

(i) effective measures of redress in relation to the ~~risks posed~~ ***damage caused*** by an AI system, with the exclusion of claims for ***direct or indirect*** damages; ***(AM 1542)***

(ii) effective measures to prevent or substantially minimise those risks.

~~2a. The Commission is also empowered to adopt delegated acts in accordance with Article 73 to remove use-cases of high-risk AI systems from the list in Annex III if the conditions referred to in paragraph 1 are no longer met (AM 1548)~~

3. ~~When assessing whether an AI system poses a risk of harm to the health and safety or risk of adverse impact on fundamental rights that is equivalent or greater than the risk of harm posed by the high-risk AI system~~, When assessing an AI system for the purposes of paragraphs 1 or 1a ~~the addition of an area or of a use-case of high-risk AI system for the purposes of paragraph 1~~, the Commission shall consult the AI Office and, where relevant, representatives of groups on which an AI system has an impact, industry, independent experts, social partners (AM 1490), and civil society organisations. The Commission shall also organise public consultations in this regard and shall make the results of those consultations and of the final assessment publicly available. (AMs 87, 88, 89, 1466, 1467, 1546, 1551, 1552, 1547);

4. The AI Office, ~~and~~national supervisory authorities or the European Parliament may request the Commission to reassess the risk categorisation in accordance with paragraph 1 and 1a. The AI system shall then be reviewed for reassessment and may be re-categorized. The Commission shall give reasons for its decision and make them public. (AM 1550)

Obtenu par CONTEXTE

COMP AM 11b on matching recitals

AMs 519-543 Covers: 19 (Rapp.), 20 (Rapp.), 21 (Rapp.), 22 (Rapp.), 519 (Greens), 521 (EPP), 522 (EPP), 524 (S&D), 525 (S&D), 527 (RE), 528 (Left), 530 (Greens), 532 (EPP), 534 (RE), 535 (EPP), 537 (EPP), 539 (Greens),

Falls: 520 (EPP), 523 (ID), 526 (ID), 529 (EPP), 533 (EPP), 536 (ID), 538 (RE), 540 (Left), 541 (EPP), 542 (Left), 543 (S&D)

Parked: 531 (Greens) - article on environment

(27) High-risk AI systems should only be placed on the Union market***,*** put into service ***or used (AM 19, 525)*** if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law, ***including fundamental rights, democracy, the rule or law or the environment (AM 19, 519, 524, 525, 527, 528)***. ***In order to ensure alignment with sectoral legislation and avoid duplications, requirements for high-risk AI systems should take into account sectoral legislation laying down requirements for high-risk AI systems included in the scope of this Regulation, such as Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices or Directive 2006/42/ EC on Machinery (AM 521, 522).*** AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any. ***Given the rapid pace of technological development, as well as the potential changes in the use of AI systems, the list of high-risk areas and use-cases in Annex III should nonetheless be subject to permanent review through the exercise of regular assessment (AM 519).***

(28) AI systems could ***have an*** adverse ***impact (AM 530)*** to health and safety of persons, in particular when such systems operate as ***safety (AM 20)*** components of products. Consistently with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and perform their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate.

(28a) The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information,

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freedom of assembly and of association, and non-discrimination, consumer protection, workers' rights, rights of persons with disabilities, right to an effective remedy and to a fair trial, right of defence and the presumption of innocence, right to good administration. In addition to those rights, it is important to highlight that children have specific rights as enshrined in Article 24 of the EU Charter and in the United Nations Convention on the Rights of the Child (further elaborated in the UNCRC General Comment No. 25 as regards the digital environment), both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons ***(AM 20, 21)***.

(29) As regards high-risk AI systems that are safety components of products, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council[9], Regulation (EU) No 167/2013 of the European Parliament and of the Council[10], Regulation (EU) No 168/2013 of the European Parliament and of the Council[11], Directive 2014/90/EU of the European Parliament and of the Council[12], Directive (EU) 2016/797 of the European Parliament and of the Council[13], Regulation (EU) 2018/858 of the European Parliament and of the Council[14], Regulation (EU) 2018/1139 of the European Parliament and of the Council[15], and Regulation (EU) 2019/2144 of the European

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9 Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

10 Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

11 Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

12 Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

13 Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

14 Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

15 Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

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Parliament and of the Council[16], it is appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment***, market surveillance (AM 532)*** and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant future delegated or implementing acts on the basis of those acts.

(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation ***listed in Annex II of this Regulation (AM 535)***, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure ***in order to ensure compliance with essential safety requirements (AM 534)*** with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices.

(31) The classification of an AI system as high-risk pursuant to this Regulation should not (***AM 537)*** mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council[17] and Regulation (EU) 2017/746 of the European Parliament and of the Council[18], where a third-party conformity assessment is provided for medium-risk and high-risk products.

(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 ***and that are listed in one of the areas and use cases in Annex III***, it is appropriate to classify them as high-risk if, in the light of their intended purpose, they pose a ***significant (AM 539)*** risk of harm to the health and safety or the fundamental rights of persons,

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16 Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

17 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

18 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

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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 ***this (AM 22)*** 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.

(32a) Providers whose AI systems fall under one of the areas and use cases listed in Annex III that consider their system does not pose a significant risk of harm to the health, safety or fundamental rights should inform the national supervisory authorities by submitting a reasoned notification. This notification could take the form of a one-page summary of the relevant information on the AI system in question, including its intended purpose and the reasons why it would not pose a significant risk of harm to the health, safety and fundamental rights. The Commission should develop guidelines in order to specify criteria to enable companies to assess whether their system would pose such risks, as well as issue a template of the notification. Providers should submit the notification as early as possible in the development stage and any case prior to the placing of the AI system on the market or its putting into service. Providers should be free to place their AI system on the market at any given time after the notification. However, if the authority estimates the AI system in question was misclassified, it should object to the notification within a period of three months. Providers who have misclassified their AI system and have placed it on the market or put it into service or into use during the periode of 3 months following the notification should be subject to substantial fines. The objection should be substantiated and duly explain why the AI system has been misclassified. Providers should retain the right to appeal the objection by providing further arguments. If after the three months there has been no objection to the notification, national supervisory authorities could still intervene if the AI system presents a risk at national level, as for any other AI system on the market. To simplify the notification process and reduce bureaucratic overhead for companies, companies operating in two or more member states should be able to submit the notification to the AI Office. Upon receipt of a notification, the AI Office should coordinate with the national supervisory authorities of the member states involved and, in the case of an objection, transmit that objection to the companies, thus acting as a single point of contact for such companies opeating in two or more member states. National supervisory authorities should submit annual reports to the AI Office detailing the notifications received and how many objections were made.

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AI ACT - COMPROMISE AMENDEMENTS - BATCH 5 - V5-23.01.2023

Chapter 2: Requirements for high-risk AI systems

COMP 2a:

Covers: AMs 1553 (Greens), 1555 (RE), 1556 (EPP), 1557 (EPP), 1559 (RE), 1563 (S&D), 1564 (The Left), 1565 (Greens), 1566 (S&D), 1568 (TheLeft)
Falls: AMs 1554 (ID), 1558 (RE), 1560 (Greens), 1562 (Greens), 1567 (EPP), 1569 (EPP), 1570 (EPP), 1571 (RE)
Parked: AMs 1561

Article 8
Compliance with the requirements

1. High-risk AI systems shall comply with the requirements established in this Chapter ***~~throughout the entire lifetime of the AI system, which includes their placing on the market as well as their putting into service and use (AM 1553)~~***.

1a. In complying with the requirement established in this Chapter, due account shall be taken of guidelines developed as referred to in Article XX, the generally acknowledged state of the art, including as reflected in the relevant harmonised standards and common specifications as referred to in articles 40 and 41 or those already set out in union harmonisation legislation. (AM 1555, 1556, 1557, 1559).

2. The intended purpose of the high-risk AI system, ***[the reasonably ~~foreseeable uses and~~ foreseeable misuses (AM 1563, 1564, 1565, 1566, 1568)]*** and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

3a. As long as the requirements of Title III, Chapters 2 and 3 or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems are addressed by Union Harmonisation Legislation listed in Annex II, Section A, the requirements or obligations of those Chapters of this Regulation shall be deemed to be fulfilled, as long as they include the AI component. Requirements of Chapters 2 and 3 of Title III or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems not addressed by Union Harmonisation Legislation listed in Annex II Section A, shall be incorporated into that Union Harmonisation Legislation, where applicable. The relevant conformity assessment shall be carried out as part of the procedures laid out under Union Harmonisation Legislation listed in Annex II, Section A.

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COMP AM 2b

Covers: AMs 90, 92, 93 (Rapp), 1572 (RE), 1576 (EPP), 1577 (TheLeft), 1578 (Greens), 1579 (EPP), 1580 (TheLeft), 1581 (Greens), 1582 (TheLeft), 1583 (S&D), 1584 (RE), 1585 (EPP), 1587 (RE), 1588 (EPP), 1597 (EPP), 1598 (RE), 1600 (EPP), 1601 (RE), 1603 (EPP), 1605 (RE), 1607 (ECR), 1609 (RE), 1610 (Greens), 1611 (EPP), 1614 (RE), 1617 (ECR), 1618 (EPP), 1619 (TheLeft), 1620 (ECR), 1621 (RE), 1625 (Greens), 1627 (RE), 1628 (EPP), 1629 (RE), 1630 (Greens), 1634 (EPP), 1639 (RE), 1641 (EPP), 1648 (EPP), 1653 (RE), 1656 (Greens); 1657 (EPP), 1659 (RE), 1660 (Greens), 1661 (EPP), 1662 (Greens), 1663 (Greens), 1664 (Greens), 1666 (Greens), 1667 (Greens), 1668 (ECR), 1669 (RE), 1670 (EPP), 45 (JURI)

Falls: AMs 91 (Rapp), 1573 (EPP), 1574 (EPP), AMs 1575(RE), 1586 (Greens), 1589 (ID), 1591 (RE), 1592 (EPP), 1593 (Left), 1594 (S&D), 1595 (EPP), 1596 (Greens), 1599 (ID), 1602 (RE), 1604 (ID), 1606 (Greens), 1608 (ID), 1612 (The Left), 1613 (EPP), 1615(S&D) 1616 (EPP), 1622 (ID), 1623 (ID), 1624 (RE), 1626 (ECR), 1629 (RE), 1631 (Greens), 1635 (ECR), 1636 (ID), 1637 (ID), 1638 (ID), 1640 (ECR), 1643 (ID), 1645 (Greens), 1646 (ID), 1649 (ID), 1650 (ID), 1651 (ID) 1652 (ID), 1654 (ID), 1658 (ECR), 1665 (Greens), 1671 (Greens)

Parked: 1590 (S&D), 1632 (Greens), 1633 (S&D) ; 1642 (Greens), 1644 (The Left), 1647 (The Left), 1655 (The Left), 42 (CULT), 44 (JURI)

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Article 9

Risk management system

1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems, ***throughout the entire ~~lifetime~~ lifecycle of the AI system (AM 1577, 1578)***. ***The risk management system can be integrated into, or a part of, already existing risk management procedures relating to the relevant Union sectoral legislation insofar as it fulfils the requirements of this article (AM 1572, 1576, 1579).***

2. The risk management system shall consist of a continuous iterative process run throughout the entire ***lifecycle ~~lifetime~~***of a high-risk AI system, requiring regular ***review and updating of the risk management process, ~~including when the high-risk AI system is subject to significant changes~~, to ensure its continuing effectiveness, and documentation of any significant decisions and actions taken subject to this Article (AM 1579, 1580, 1581)*** ***~~systematic updating~~***. It shall comprise the following steps:

   (a) identification***, estimation and evaluation*** ~~and analysis~~ of the known and ***the reasonably*** foreseeable risks ***that the ~~associated with each~~*** high-risk AI system ***can pose to (AM 90) the health or safety of natural persons, their fundamental rights ~~or their~~ including equal access and opportunities, democracy and rule of law or the environement when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse. (AM90, 1582, 1583, 1584, 1585, 1587, 1588, 1666, 1667)***

~~(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;~~

(b) evaluation of ~~***other possibly arising***~~ ***emerging significant (AM 1597, 1598)*** ~~arising~~ risks ***as described in paragraph 2(a) (AM 1597) and identified*** based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

(c) adoption of ~~***suitable***~~ ***appropriate and targeted*** risk management measures ***designed to address*** ~~***known and reasonably foreseeable risks***~~ ***the risks identified pursuant to letter a and b of this paragraph (AM 1600, 1601)*** in accordance with the provisions of the following paragraphs.3. The risk management measures referred to in paragraph 2, point (c) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2, ***with a view to mitigate risks effectively while ensuring an appropriate and proportionate implementation of the requirements (AM 1603, 1605)***. ~~They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications.~~

4. The risk management measures referred to in paragraph 2, point (c) shall be such that ***relevant (AM 1614)*** residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is ***reasonably*** judged ***to be (AMs 1607, 1609, 1611)*** acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks ***and the reasoned judgements made (AM 1610)*** shall be communicated to the ~~user~~ ***deployer***.

In identifying the most appropriate risk management measures, the following shall be ***ensured***: ~~***pursued***~~ ***(AM 1617)***

(a) elimination or reduction of ***identified*** ~~***and evaluated***~~ risks as far as ***technically feasible*** ~~***possible***~~ ~~***in the light of the generally acknowledged state of the art and industry standards***~~ through adequate design and development ***of the high-risk AI system (AM 1618, 1620, 1621), involving when relevant, experts*** ~~***and internal***~~ ***and external stakeholders (AM 1619)***;

(b) where appropriate, implementation of adequate mitigation and control measures ~~***in relation to***~~ ***addressing significant (AMs 1598, 1625)*** risks that cannot be eliminated;

(c) provision of ***the required (AM 1628)*** ~~adequate~~ information pursuant to Article 13, ~~***in particular as regards the risks referred to in paragraph 2, point (b) of this Article (AM 1627, 1628)***~~ and, where appropriate, training to ~~users~~ ***deployers***.

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In eliminating or reducing risks related to the use of the high-risk AI system, ***providers shall take into (AM 1634)*** due consideration ~~***shall be given to***~~ the technical knowledge, experience, education, ***and*** training ~~***to be expected by***~~ the ~~user~~ ***deployer may need, including in relation to*** ~~***and***~~ the ***presumable context of use (AM 92)*** ~~in which the system is intended to be used~~.

5. High-risk AI systems shall be ~~***evaluated***~~ ***tested*** for the purposes of identifying the most appropriate ***and targeted*** risk management measures ***and weighing any such measures against the potential benefits and intended goals of the system***. ~~***Evaluation***~~ ***Testing*** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the ~~***relevant***~~ requirements set out in this Chapter ***(AM 1639, 1641)***.

6. ~~***Evaluation***~~ ***Testing*** procedures shall be suitable to achieve the intended purpose of the AI system ~~***and do not need to go beyond what is necessary to achieve that purpose. (AM 93, 1648)***~~

7. ~~***Evaluation***~~ ***The testing*** of the high-risk AI systems shall be performed, ~~***as appropriate, at any point in time throughout the development process, and, in any event, (AM 1653)***~~ prior to the placing on the market or the putting into service. ~~***Evaluation***~~ ***Testing*** shall be made against ~~***preliminarily***~~ ***prior*** defined metrics, and probabilistic thresholds that are appropriate to the intended ***purpose or reasonably foreseeable misuse*** ~~purpose~~ ***(AM 1656)*** of the high-risk AI system ***(AM 1657)***.

8. When implementing the risk management system described in paragraphs 1 to 7, ***providers shall give*** specific consideration ~~***shall be given***~~ ***(AM 1661)*** to whether the high-risk AI system is likely to ***adversely impact vulnerable groups of people or children (1664).***

9. For ***providers and AI systems already covered by Union law that require them to establish a specific risk management, including credit institutions regulated by Directive 2013/36/EU,*** the aspects described in paragraphs 1 to 8 shall be part of ***or combined with*** the risk management procedures established by ***those acts of Union law*** ~~***those institutions pursuant to Article 74 of that Directive.***~~ ***(AM 1668, 1669, 1670, JURI 45)***

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COMP AM 2c

Covers: AMs 94 (Rapp); 95 (Rapp); 96 (Rapp), 97 (Rapp); 98 (Rapp); 99 (Rapp); 1672 (The Left); 1673 (RE); 1674 (EPP); EPP (1675); 1678 (S&D); 1679 (S&D); 1680 (S&D); 1682 (ECR); 1683 (RE); 1684 (Greens); 1685 (EPP); 1686 (S&D); 1690 (S&D); 1691 (EPP); 1692 (EPP); 1693 (RE); 1694 (S&D); 1699 (EPP),1701 (S&D); 1704 (ECR); 1706 (RE); 1708 (EPP); 1709 (EPP); 1710 (Greens), 1712 (The Left); 1715 (RE); 1716 (ECR); 1718 (S&D); 1719 (S&D); 1720 (ECR); 1721 (EPP); 1722 (Greens); 1728 (The Left); 1732 (S&D), 1734 (ID); 1735 (Greens); 1736 (S&D); 1737 (The Left); 1742 (RE); 1743 (EPP); 1745 (EPP); (1746 - Greens, 1747 - MEPs); ITRE 41

Falls: AMs 100 (Rapp); 1676 (EPP); 1677 (ECR); 1681 (The Left); 1685 (EPP); 1687 (ID); 1688 (EPP); 1689 (S&D); 1695 (The Left); 1696 (EPP); 1697 (ECR); 1698 (ECR);; 1700 (ECR); 1702 (RE); 1703 (The Left); 1705 (EPP); 1707 (RE); 1711 (S&D); 1713 (EPP); 1714 (EPP); 1717 (ID); 1723 (EPP); 1724 (EPP); 1725 (EPP); 1726 (EPP); 1727 (EPP); 1730 (RE); 1731 (ECR); 1733 (EPP); 1738 (EPP); 1739 (The Left); 1740 (ECR); 1741 (ID); 1744 (ID);

Parked: 1729 (S&D) (indeterminate uses), 1746 (Greens) (evironmental impact), 1747 (risk management for children)

Article 10
Data and data governance

1. High-risk AI systems which make use of techniques involving the training of models with data shall be~~***, as far as this is technically feasible, taking into account the state of the art,***~~ ***(AMs 1673, 1674, 1675, ITRE 35)*** developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 ***as far as this is technically feasible according to the specific market segment or scope of application***.

   Techniques that do not require labelled input data, such as unsupervised learning and reinforcement learning ~~***that do not use validation and testing data sets***~~ ***shall be developed on the basis of*** ~~***training***~~ ***data sets, such as for testing and verification that meet the quality criteria referred to in paragraphs 2 to 5. (AMs 1672; 1679, 1680, 1742, ITRE 36).***

~~***1a. Validation datatsets shall be separate datasets from both the testing and the training datasets. (AM 1678).***~~

2. Training, validation and testing data sets shall~~***, for the entire lifetime of the AI system, (AM 1682, 1684; 1685, 1686, ITRE 38)***~~ be subject to~~ appropriate~~ ***(AM 1683)*** data governance ~~and ***risk management measures (AMs 1682)***~~ ***appropriate for*** ~~***the context of use as well as***~~ ***the intended purpose of the AI system (AM 1683, 1709)*** ~~management practices.~~ Those practices ~~***measures***~~ shall concern in particular,

   (a) the relevant design choices;

   (aa) transparency as regards the original purpose of data collection; (ITRE 39)

   (b) data collection ***processes (AMs 1690; 1691, ITRE 40)*** ~~***including verification of the legality of the sources of the data. (AM 1710)***~~

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(c) ~~relevant~~ ***(AMs 1692, 1693, 1694)*** data preparation processing operations, such as annotation, labelling, cleaning, ***updating (AM 94)*** enrichment and aggregation;

(d) the formulation of ~~relevant~~ ***justified and reasonable (AM 1695)*** assumptions, notably with respect to the information that the data are supposed to measure and represent;

(e) a***n*** ~~prior~~ assessment of the availability, quantity and suitability of the data sets that are needed;

(f) examination in view of possible biases ***that are likely to affect the health and safety of persons, negatively impact fundamental rights or lead to discrimination prohibited under Union law (AMs 1699, ITRE 41)***, ***especially where data outputs influence inputs for future operations ('feedback loops') and (AM 1701)***

(fa) appropriate measures to detect, prevent and mitigate possible biases; (AM 95)

(g) the identification of ~~any~~ ***(AM 1708, ITRE 42)*** ~~possible~~ ***relevant (AM 1706)*** data gaps or shortcomings ~~***that increase the risks of harm to fundamental rights, health, safety or the environment (AM 1704) to such an extent***~~ ***that it prevent compliance with this Regulation***, and how those gaps and shortcomings can be addressed.

~~***(g a) verification of the legality of the sources of the data. (AM 1710)***~~

~~***(gb) the presumable context of the use as well as the intended purpose of the AI System (AM 1709)***~~

~~***(ga) the purpose and the environment context in which the system is to be used. (ITRE 43)***~~

3. Training ***datasets, and where they are used*** ~~***applicable***~~, validation and testing datasets, ***including the labels (1718)***, shall be relevant, ***sufficiently*** representative, ~~***up-to-date, and to the best extent possible, taking into account the state of the art and in accordance with industry standards,***~~ ***(AMs 96; 1715; 1716; 1718; 1720; 1721)*** ~~free of~~ ***appropriately vetted for*** errors and ***be as*** complete ***as possible (AM 96) in view of the intended purpose***. ***(ITRE 44)*** They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons ~~on which~~ ***in relation to whom (AM 1722)*** the high-risk AI system is intended to be used. These characteristics of the datasets ~~may~~ ***shall (AMs 1712; 1718; 1719)*** be met at the level of individual datasets or a combination thereof.

4. ~~Training, validation and testing d~~ ***D***atasets ***(AM 1732)*** shall take into account, to the extent required by the intended purpose ***or reasonably foreseeable*** ~~***uses or***~~ ***misuses of the AI system (AMs 1728; 1729; 1732)***, the characteristics or elements that are particular to the specific geographical, ~~***cultural***~~ ***contextual (AMs 97, 1709, ITRE 45)*** behavioural or functional setting within which the high-risk AI system is intended to be used.

~~5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the~~

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~~providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.~~ ***(AM 98; 1734, 1735; 1736; 1737)***

6. Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that those high-risk AI systems comply with paragraph 2.

6a. Where the provider cannot comply with the obligations laid down in this Article because it does not have access to the data and the data is held exclusively by the ~~user~~ deployer, the ~~user~~ deployer may, on the basis of a contract, be made responsible for any infringement of this Article. (AMs 99, 1745)

6c. ~~Providers and users deployers may comply with the obligations set out in this Article through the use of third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices. (AM 1743, ITRE 37)~~

Recital

(44) ***~~Having accessible and~~ Hi***gh data quality ***play a vital role in ensuring*** ~~is essential for~~ ***(AM 623)*** 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~~ ***a (AM 628)*** 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. ***The data collection process should also include a verification of the legality of the sources of said data, such as compliance with applicable legislation on intellectual property rights, trade secrets or personal data protection (AM 1710).*** Training, ***and where applicable,*** validation and testing data sets***, including the labels, (AM 629)*** should be sufficiently relevant, representative***, ~~up-to-date,~~*** ~~and~~ ***appropriately vetted for*** ~~free of~~ errors ***(ITRE 6)***and ***as*** complete ***as possible*** 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 ***in relation to whom*** ~~on which~~ ***(AM 628)*** the high-risk AI system is intended to be used, ***with specific attention to the mitigation of possible biases in the datasets, that might lead to risks to fundamental rights or discriminatory outcomes for the persons affected by the high-risk AI system***. ***(ITRE 6) Biases can for example 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~~ Results provided by ~~an~~ AI systems ~~is~~ are ~~necessarily~~ influenced by ~~the quality of the data used, and~~ such inherent biases that are***

Obtenu par CONTEXTE

inclined to gradually increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain vulnerable or ethnic groups, or racialised communities. (AM 631) 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, ***contextal, (AM 628, ITRE 6),*** 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***, exceptionally and following the application of all applicable conditions laid down under this Regulation and the Regulation (EU) 2016/679, Directive (EU) 2016/680 and Regulation (EU) 2018/1725,*** be able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the ***negative*** bias ~~monitoring~~, detection and correction in relation to high-risk AI systems. ***Negative bias should be understood as bias that create direct or indirect discriminatory effect against a natural person***. ***The requirements related to data governance can be complied with by having recourse to third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices. (AM 1743, ITRE 37)***

COMP AM 2d

Covers: AMs 101 (Rapp); 1750 (EPP); 1751 (ID); 1752 (EPP); 1753 (RE); 1754 (RE); 1755 (S&D); 1756 (EPP); 1759 (RE); 1764 (S&D)

Falls: AM 1748 (EPP); 1749 (Greens); 1757 (EPP); 1758 (EPP); 1760 (EPP); 1761 (EPP); 1762 (EPP); 1763 (ID)

Parked: AM 1755 (S&D) (linked to enforcement chapter)

Article 11
Technical documentation

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

   The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national ***supervisory*** authorities and notified bodies with ~~all~~ ***(AM 1756)*** the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV ***or, in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority***. ***(AMs 1750, 1751, 1752, 1753, 1754)***

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in ~~Annex IV~~ ***paragraph 1 (AM 1759)*** as well as the information required under those legal acts.

Obtenu par CONTEXTE

3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.

3 a. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive. (AM 1764)

Obtenu par CONTEXTE

COMP AM 2e

Covers: AMs 102 (Rapp); 103 (Rapp); 1768 (Greens); 1771 (EPP); 1773(S&D); 1774 (The Left); 1776 (EPP); ***1781 (TheLeft), 1782 (S&D), 1783 (S&D)***

Falls: 1765 (ID); 1766 (RE); 1767 (EPP); 1769 (ECR); 1770 (The Left); 1772 (EPP); 1777 (ECR); 1775 (ECR); ***1778 (RE), 1779 (EPP), 1780 (ID),*** 1784 (The Left), 1785 (The Left), 1786 (The Left); 1787 (The Left)

Parked: ~~***1778 (RE) (linked to Annex III); 1779 (EPP) (linked to Annex III); 1780 (ID) (linked to Annex III); 1781 (The Left) (linked to Annex III); 1782 (S&D) (linked to Annex III); 1783 (S&D) (linked to Annex III);***~~

Article 12
Record-keeping

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to ***the state of the art and (AM 1768)*** recognised standards or common specifications.

2. ~~The logging capabilities shall~~ ***In order to (AM 1771)*** ensure a level of traceability of the AI system's functioning throughout its ***entire (AM 102)*** life***time*** that is appropriate to the intended purpose ~~***or reasonably foreseeable use (AMs 1773; 1774)***~~ of the system***, the logging capabilities shall facilitate the monitoring of operations as referred to in Article 29(4) as well as the post market monitoring referred to in Article 61 (AMs 103; 1771). In particular, they shall enable the recording of events relevant for the identification of situations that may:***

(i) result in the AI system presenting a risk within the meaning of Article65(1); or

(ii) lead to a substantial modification of the AI system;

~~3. In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-market monitoring referred to in Article 61.~~ (***AM 1776)***

4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:

(a) recording of the period of each use of the system (start date and time and end date and time of each use);

(b) the reference database against which input data has been checked by the system;

(c) the input data for which the search has led to a match;

(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).

Obtenu par CONTEXTE

COMP AM 2d':

Covered: AMs 298 (Rapp.), 299 (Rapp.), 300 (Rapp.), 301 (Rapp.), 302 (Rapp.), 303 (Rapp.), 304 (Rapp.), 305 (Rapp.), 3243 (Greens), 3247 (EPP), 3248 (Greens), 3249 (Greens), 3250 (Greens), 3251 (S&D), 3254 (EPP), 3255 (EPP), 3256 (EPP), 3257 (Greens) 3258 (Greens), 3261 (EPP), 3264 (EPP), 3267 (Greens)3268 (EPP), 3269 (S&D), 3271 (EPP), 3273 (S&D), 3274 (S&D), 3275 (S&D), 3276 (S&D), 3277 (Greens), 3279 (RE), 3280 (RE), 3281 (RE), 3263 (Greens),

Fall: 3244 (S&D), 3245 (Left), 3246 (S&D), 3252 (EPP), 3282 (Left), 3278 (EPP), 3264 (EPP), 3265 (EPP), 3266 (Greens), 3270 (Left), 3259 (EPP), 3260 (ECR), 3262 (ECR)

Parked: 3272 (Left)

ANNEX IV
TECHNICAL DOCUMENTATION referred to in Article 11(1)

The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:

1. A general description of the AI system including:

   (a) its intended purpose ~~***or reasonably foreseeable use (AMs 3244, 3245, 3246)***~~, ***the name of the provider (AM 3247)*** and the version of the system ***reflecting its relation to previous and, where applicable, more recent, versions in the succession of revisions***; ***(AM 3243)***

   (aa) the ~~categories and~~ nature of data likely or intended to be processed by the system and, in the case of personal data, the categories of natural persons and groups likely or intended to be affected (AM 3248, 3249);

   (b) how the AI system ***can*** interacts ~~or can be used to interact~~ with hardware or software***, including other AI systems, that are (AM 3250, 3251),*** not part of the AI system itself, where applicable;

   (c) the versions of relevant software or firmware and***, where applicable, information for the ~~user~~ deployer on (3254)*** any requirement related to version update;

   (d) the description of ***the various configurations and variants of*** the AI system ***which are intended to be (AM 3255)*** placed on the market or put into service;

   (e) the description of hardware on which the AI system is intended to run;

   (f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;

   (fa) the description of the ~~user~~ deployer interface (AM 3256);

   (g) instructions of use for the ~~user~~ ***deployer in accordance with Article 13(2) and (3) (AM 298) as well as 14(4)(e) (AM 3258)*** and, where applicable installation instructions;

Obtenu par CONTEXTE

~~*(ga) a description of how the AI system works and examples of representative use cases for which the AI system is intended (AM 299);*~~

~~*(gb) where applicable, a detailed and easily intellegible description of the expected input variables and the expected input data quality (AM 300);*~~

(gc) a detailed and easily intellegible description of the system's main optimisation goal or goals (AM 301);

(gd) a detailed and easily intellegible description of the system's expected output and expected output quality (AM 302);

(ge) detailed and easily intellegible instructions for interpreting the system's output (AM 303);

(gf) examples of scenarios for which the system should not be used (AM 304).

2. A detailed description of the elements of the AI system and of the process for its development, including:

(a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;

(b) ***a description of*** the ***architecture,*** ~~***and***~~ design specifications ~~of the system, , of the~~ ***algorithms and the data structures (AM 3263)~~~~: a description of the AI system architecture, with~~~~*** including a decomposition of its components and interfaces, how they relate to one another and how they provide for the overall processing or logic of the AI system (AM. 3261)***; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

~~(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;~~ ***(AM 3264)***

(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the ~~users~~ ***deployers***, in accordance with Articles 13(3)(d);

Obtenu par CONTEXTE

(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness, ~~cybersecurity~~ ***(AM 3268)*** and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f);

(ga) cybersecurity measures put in place (AM 3271).

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

3a. A description of the appropriateness of the performance metrics for the specific AI system (AMs 3269, 3273, 3274);

3b. ~~Detailed~~ Information about ~~the carbon footprint and~~ the energy consumption ~~efficiency of~~ the AI system during ~~with regard to~~ the development phase and ~~in particular with regard to computational resources, algorithm design and training processes (AMs 3275, 3277), as well as~~ the expected energy consumption during use, taking into account, where applicable, relevant Union and national legislation (AM 3276);

4. A detailed description of the risk management system in accordance with Article 9;

5. A description of any ***relevant*** change made ***by providers (AMs 3279, 3280)*** to the system through its ***~~lifetime~~*** lifecycle;

6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of ***~~common specifications~~ or (AM 305, 3281)*** other relevant standards, ~~and technical specifications~~ ***or common specifications*** applied

7. A copy of the EU declaration of conformity;

Obtenu par CONTEXTE

8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).

RECITALS

Covers: 613 (RE); 615 (Greens); 618 (Greens); 619 (S&D); 623 (EPP); 628 (Greens); 629 (S&D); 631 (S&D); 633 (EPP);

Falls: 614 (EPP); 616 (The Left); 617 (The Left); 620 (The Left); 621 (The Left); 624 (ID); 625 (EPP); 626 (The Left); 627 (The Left); 630 (EPP); 632 (ID); 634 (EPP); 635 (Greens); 636 (EPP)

Parked: 622 (EPP) - fundamental rights impact assessment

(42) To mitigate the risks from high-risk AI systems placed or otherwise put into service on the Union market for ~~users~~ ***deployers (AM 615)*** and affected persons, certain mandatory requirements should apply, taking into account the intended purpose, ***the reasonably foreseeable misuse (AM 615)*** of the system and according to the risk management system to be established by the provider. ***These requirements should be objective-driven, fit for purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators. (AM 613)***

(43) Requirements should apply to high-risk AI systems as regards the quality ***and relevance (AM 618)*** of data sets used, technical documentation and record-keeping, transparency and the provision of information to ~~users~~ *deployers*, human oversight, and robustness, accuracy and cybersecurity. Those requirements are necessary to effectively mitigate the risks for health, safety and fundamental rights, as ***well as the environment, democracy and rule of law, as (AMs 618, 619)*** applicable in the light of the intended purpose ***or reasonably foreseeable misuse (AM 618)*** of the system, and no other less trade restrictive measures are reasonably available, thus avoiding unjustified restrictions to trade.

(44) ~~***Having accessible and***~~ ***Hi***gh data quality ***play a vital role in ensuring*** ~~is essential for~~ ***(AM 623)*** 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~~ ***a (AM 628)*** source of discrimination prohibited by Union law. High quality training, validation and testing

Obtenu par CONTEXTE

data sets require the implementation of appropriate data governance and management practices. ***The data collection process should also include a verification of the legality of the sources of said data, such as compliance with applicable legislation on intellectual property rights, trade secrets or personal data protection (AM 1710).*** Training, ***and where applicable,*** validation and testing data sets***, including the labels, (AM 629)*** should be sufficiently relevant, representative***,*** ~~***up-to-date,***~~ ~~and~~ ***appropriately vetted for*** ~~free of~~ errors ***(ITRE 6)***and ***as*** complete ***as possible*** 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 ***in relation to whom*** ~~on which~~ ***(AM 628)*** the high-risk AI system is intended to be used, ***with specific attention to the mitigation of possible biases in the datasets, that might lead to risks to fundamental rights or discriminatory outcomes for the persons affected by the high-risk AI system***. ***(ITRE 6) Biases can for example 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***~~ ***Results provided by*** ~~***an***~~ ***AI systems*** ~~***is***~~ ***are*** ~~***necessarily***~~ ***influenced by*** ~~***the quality of the data used, and***~~ ***such inherent biases that are inclined to gradually increase and thereby perpetuate and amplify existing discrimination, in particular for persons belonging to certain vulnerable or ethnic groups, or racialised communities. (AM 631)*** 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, ***contextal, (AM 628, ITRE 6),*** 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. ***The requirements related to data governance can be complied with by having recourse to third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices. (AM 1743, ITRE 37)***

(45) For the development ***and assessment (AM 633)*** 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.

Obtenu par COMETE

45a) ***The right to privacy and to data protection must be guaranteed throughout the entire lifecycle of the AI system. In this regard, the principles of data minimisation and data protection by design and by default, as set out in Union data protection law, are essential when the processing of data involves significant risks to the fundamental rights of individuals. Providers and users of AI systems should implement state-of-the-art technical and organisational measures in order to protect those rights. Such measures should include not only anonymisation and encryption, but also the use of increasingly available technology that permits algorithms to be brought to the data and allows valuable insights to be derived without the transmission between parties or unnecessary copying of the raw or structured data themselves (AM 30)***

(46) Having ***comprehensible (ITRE 7)*** information on how high-risk AI systems have been developed and how they perform throughout their ~~lifecycle~~ ***lifetime (AM 636)*** 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. ***AI systems can generate important energy consumption during their lifecyle. In order to better apprehend the impact of AI systems on the environment, the technical documentation drafted by providers should include information on the energy consumption of the AI system, including the ~~expected~~ consumption during development and expected consumption during use. Such information should take into account the relevant Union and national legislation. To ensure that a single documentation is possible, terms and definitions related to the required documentation and any required documentation in the relevant Union legislation should be aligned as much as possible (AM 1761).***

Obtenu par CONTEXTE

Covered:, 105 (Rapp.), 106 (Rapp.), 107 (Rapp.), 108 (Rapp.), 109 (Rapp.), 1881 (EPP), 1882 (S&D), 1883 (S&D), 1885 (Greens), 1886 (S&D), 1887 (RE), 1888 (EPP), 1890 (EPP), 1891 (RE), 1893 (RE), , 1899 (RE), 1900 (EPP), 1901 (EPP), 1904 (EPP),
Falls: 104 (Rapp.), 1876 (EPP), 1878 (ECR), 1879 (EPP), 1880 (EPP), 1887 (RE), 1889 (Greens), 1892 (ID), 1894 (Left), 1895 (Greens), 1896 (Left), 1897 (EPP), 1898 (ID), 1902 (RE), 1905 (Left), 1907 (Left), 1908 (ECR),
Parked: 1874-1875-1877 (Greens) - deployers vs. users, 1884 (RE) - general purpose AI, 1903 (S&D) - governance, 1906 (ECR) - fundamental rights impact assessment, 1909 (RE) linked to Articles 29-29a

Chapter 3

Obligations of providers, and*deployers* of high-risk AI systems and other parties

AI ACT - COMPROMISE AMENDEMENTS

BATCH 3 - FINAL

COMP AM 3a

Covered:, 105 (Rapp.), 106 (Rapp.), 107 (Rapp.), 108 (Rapp.), 109 (Rapp.), ***1874 (Greens), 1875 (Greens), 1877 (Greens),*** 1881 (EPP), 1882 (S&D), 1883 (S&D), 1885 (Greens), 1886 (S&D), 1887 (RE), 1888 (EPP), 1890 (EPP), 1891 (RE), 1893 (RE), 1899 (RE), 1900 (EPP), 1901 (EPP), ***1903 (S&D),*** 1904 (EPP),
Falls: 104 (Rapp.), 1876 (EPP), 1878 (ECR), 1879 (EPP), 1880 (EPP), 1887 (RE), 1889 (Greens), 1892 (ID), 1894 (Left), 1895 (Greens), 1896 (Left), 1897 (EPP), 1898 (ID), 1902 (RE), 1905 (Left), 1907 (Left), 1908 (ECR),
Parked: ~~1874-1875-1877 (Greens) - deployers vs. users~~, 1884 (RE) - general purpose AI, ~~1903 (S&D) - governance,~~ 1906 (ECR) - fundamental rights impact assessment, 1909 (RE) linked to Articles 29-29a

Chapter 3

Obligations of providers, and ~~and (AM 104) users~~ *deployers* of high-risk AI systems and other parties

Article 16

Obligations of providers of high-risk AI systems

Providers of high-risk AI systems shall:

Obtenu par CONTEXTE

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title ***before placing them on the market or putting them into service***;

(aa) indicate their name, registered trade name or registered trade mark, and their address and contact information on the high-risk AI system or, where that is not possible, on its accompanying documentation, as appropriate; (AMs 1881, 1882, 1885)

(ab) ensure that natural persons to whom human oversight of high-risk AI systems is assigned are specifically made aware ~~and remain aware~~ of the risk of automation or confirmation bias (AM 105);

~~***(ac) ensure that the performance of the high-risk AI system is measured appropriately, including its level of accuracy, robustness and cybersecurity (AM 1883);***~~

(ad) provide specifications for the input data, or any other relevant information in terms of the datasets used, including their limitation and assumptions, taking into account the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system (AM 1886);

(b) have a quality management system in place which complies with Article 17;

(c) draw-up ***and keep*** the technical documentation of the high-risk AI system ***referred to in Article 11 (AM 1887, 1888)***;

(d) when under their control, keep the logs automatically generated by their high-risk AI systems ***that are required for ensuring and demonstrating compliance with this Regulation, in accordance with Article 20 (AM 106, 1890, 1891)***;

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service ~~***or use (AM 1896),***~~ ***in accordance with Article 43 (AM 107, 1893)***;

(ea) draw up an EU declaration of conformity in accordance with Article 48 (AM 108);

(eb) affix the CE marking to the high-risk AI system to indicate conformity with this Regulation, in accordance with Article 49 (AM 109, 1901);

(f) comply with the registration obligations referred to in Article 51;

(g) take the necessary corrective actions ***as referred to in Article 21 and provide information in that regard***~~, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title~~; ***(AM 110, 1899, 1900)***

~~(h) inform the national competent authorities of the Member States in which they made the AI system available or put it into service and, where applicable, the notified body of the non-compliance and of any corrective actions taken;~~ ***(AM 111)***

~~(i) to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;~~ ***(AM 112)***

(j) upon ***a reasoned (AM 1904)*** request of a national ***supervisory*** ~~competent~~ authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title ***(AM 1903)***

Obtenu par CONTEXTE

(k) ensure that the high-risk AI system complies with accessibility requirements.

~~***The obligations contained in paragraph 1 shall be without prejudice to the obligations applicable to providers of high-risk AI systems arising from Regulation (EU) 2016/679 of the European Parliament and of the Council and Regulation (EU) 2018/1725 of the European Parliament and of the Council (AM 1908).***~~

RECITAL

Cover: AMs

Fall: 655 (ID), 656 (Greens),

(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.

Obtenu par CONTEXTE

COMP AM 3b

Covering AMs 113, 114, 115, 1914 (RE), 1915 (EPP), 1916 (RE), 1917 (EPP), 1923 (Greens), 1925 (Greens), 1934 (RE), 1940 (EPP), 1981 (RE), 1982 (EPP),

Falls: AMs 1910 (EPP), 1911 (ID), 1912 (Greens), 1913 (The Left), 1916 (RE), 1917 (EPP), 1918 (EPP), 1919 (EPP), 1920 (EPP), 1921 (RE), 1922 (EPP), 1924 (EPP), 1925 (Greens),1926 (ID), 1927 (The Left),, 1928 (EPP), 1929 (EPP), 1930 (EPP), 1931 (S&D), 1932 (The Left), 1933 (EPP), 1935 (RE), 1936 (EPP), 1937 (EPP), 1938 (EPP), 1939 (Greens), 1940 (EPP), 1941 (ID), 1942 (Greens), 1943 (The Left), 1944 (The Left), 659 (EPP); 660 (ID); 657 (Greens), 658 (ECR); ***ENVI 42, TRAN 23***

~~*Parked (and reasons why): 1925 (Greens) "deployment" vs. "use", 1931 (S&D) and 1932 (The Left) - near misses,*~~

Article 17
Quality management system

1. Providers of high-risk AI systems shall ***have*** ~~put~~ a quality management system in place that ensures compliance with this Regulation. ~~***That system***~~ ***It (AM 113)*** shall be documented in a systematic and orderly manner in the form of written policies, procedures ***or*** ~~***and***~~ ***(AM 1914)*** instructions, and can ~~***shall be incorporated as part of***~~ ***into an existing quality management system under sectoral legislation (AMs 1915, 1940). It shall*** include at least the following aspects:

~~***(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system***~~ ***(AMs 1916, 1917)***

b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;

(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, ***or do not cover all of the relevant requirements, (AM 1923)*** the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

(f) systems and procedures for data management, including ***data acquisition (AM 1925)*** data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the

Obtenu par COMTEXTE

market or putting into service ~~*or use (AM 1927, 1925)*~~ of high-risk AI systems;

(g) the risk management system referred to in Article 9;

(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;

(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;

(j) the handling of communication with ~~national~~ ***relevant (AM 114)*** competent authorities, including sectoral ones, ~~***providing or supporting the access to data, notified bodies, other operators, customers or other interested parties***~~; ***(AM 1934)***

(k) systems and procedures for record keeping of all relevant documentation and information;

(l) resource management, including security of supply related measures;

(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. ***Providers shall in any event respect the degree of rigour and the level of protection required to ensure compliance of their AI systems with this Regulation (AM 115)***

3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.

Matching recital:

(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. ***For providers that have already in place quality management systems such as those based on ISO 9001 or other relevant standards, no duplicative quality management system in full should be expected but rather an adaptation of their existing systems to certain aspects linked to compliance with specific requirements of this Regulation. This should also be reflected in future standardization activities or guidance adopted by the Commission in this respect.*** 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

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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.

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COMP AM 3c

Covering AMs 1945 (S&D)

Fall: AMs 1046 (EPP); 1947 (EPP); 1948 (Greens);

~~*Article 18*~~

~~*Obligation to draw up technical documentation*~~

~~*1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV.*~~

~~*2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.*~~ **(AM 1945)**

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COMP AM 3d

Covering

Fall: AMs 1949 (The Left); 1950 (The Left); 1951 (ID); 1952 (The Left); AM 116 (Rapp)

~~Article 19~~

~~Conformity assessment~~

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

~~2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.~~

Obtenu par CONTEXTE

COMP AM 3e

Covering AMs 1956 (RE); 1958 (EPP);

Fall: AMs 1953 (EPP); 1954 (ID); AM 1957 (Greens)

Parked: ~~AM 1957 (Greens) "deployer" vs. "user";~~ 1955 (The Left)

Article 20
Automatically generated logs

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control ~~by virtue of a contractual arrangement with the user or otherwise by law~~. ***Without prejudice to applicable Union or national law, the*** logs shall be kept for a period ***of at least 6 months. The retention period shall be (AMs 1956 and 1958)*** ~~is appropriate~~ ~~***to***~~ ***in accordance with*** ~~in the light of~~ ***industry standards (AM 1956) and appropriate to*** the intended purpose of high-risk AI system.

2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive.

Obtenu par CONTEXTE

COMP AM 3f

Covering AMs 117 (Rapp); 118 (Rapp); AMs 1959 (EPP), 1960 (Greens), 1962 (S&D)

Fall: 1961 (ID)

Article 21
Corrective actions

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately ~~***and without delay (AM 117)***~~ take the necessary corrective actions to bring that system into conformity, to withdraw it***, to disable it (AM 1960),*** or to recall it, as appropriate. ~~***Where applicable, they shall also investigate the causes in collaboration with the user (AM 1959).***~~ ~~They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.~~

In the cases referred to in paragraph 1, providers shall immediately inform:

a. the distributors,

b. the importers,

c. the national competent authorities of the Member States in which they made the AI system available or put it into service; and

d. the ~~users~~ deployer, where possible.

The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25, and the notified body if the high-risk AI system had to undergo a third-party conformity assessment in accordance with Article 43.

Where applicable, they shall also investigate the causes in collaboration with the ~~user~~ deployer (AM 1959)

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COMP AM 3g

Covering AMs 119 (Rapp); 1963 (S&D), 1966 (Greens);

Fall: 1964 (EPP); 1965 (RE);

Article 22
Duty of information

Where the high-risk AI system presents a risk within the meaning of Article **65(1)** ***(AM 119)*** and ~~***that risk is known to***~~ the provider of the system ***becomes aware of that risk (AM 1966),*** that provider shall immediately inform the ***national supervisory authorities*** ~~***y*** authorities~~ of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular ***the nature (AM 1964)*** of the non-compliance and of any ***relevant (AM 1964)*** corrective actions taken.

In the cases referred to in paragraph 1, providers of the high-risk AI system shall immediately inform:

a. the distributors,

b. the importers,

c. the national competent authorities of the Member States in which they made the AI system available or put it into service; and

d. the ~~***users***~~ ***deployers, where possible,***

The providers shall also inform the authorised representative, if one was appointed in accordance with Article 25.

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COMP AM 3h

Covering AMs 121 (Rapp); 122 (Rapp); 1967 (RE); 1968 (EPP); 1969 (RE); 1970 (RE); 1971 (S&D) 1973 (EPP); 1974 (RE), 1975 (S&D); 2105 (ECR)

Fall: AMs 1972 (Greens), AMs 1978 (RE); 1979 (EPP)

Parked: ~~1967 (RE); 1970 (RE); 1971 (S&D)~~ ; 1976 (EPP), 1977 (RE)

Article 23

*Cooperation with competent authorities**, the Office and the Commission (AMs 120, 1967)***

Providers ***and where applicable, ~~users~~ deployers (AMs 121, 1970, 1971)*** of high-risk AI systems shall, upon ***a reasoned (AMs 1968, 1973)*** request by a national competent authority ***or where applicable, by the AI Office or the Commission, (AM 121, 1970, 1971)*** provide ~~that authority~~ ***them (AM 121)*** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. ~~***Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law (AMs 1970, 1971).***~~

Upon a reasoned request by a national competent authority or, where applicable, by the Commission, providers and, where applicable, ~~users~~ deployers shall also give the requesting national competent authority or the Commission, as applicable, access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control ~~by virtue of a contractual arrangement with the user or otherwise by law.~~ (AM 122, 1974, 1975)

Any information obtained by a national competent authority or by the Commission pursuant to the provisions of this Article shall be considered a trade secret and be treated in compliance with the confidentiality obligations set out in Article 70 (AMs 1968, 1969, 1974, 2105)

Article 24

Obligations of product manufacturers

Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.

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Matching recital:

(55) Where a high-risk AI system that is a safety component of a product which is covered by a relevant New Legislative Framework sectorial legislation is not placed on the market or put into service independently from the product, the manufacturer of the final product as defined under the relevant New Legislative Framework legislation should comply with the obligations of the provider established in this Regulation and notably ensure that the AI system embedded in the final product complies with the requirements of this Regulation.

Obtenu par CONTEXTE

COMP AM 3i

Covering AMs 123 (Rapp); 124 (Rapp), 125 (Rapp), 126 (Rapp); 1981 (RE); 1982 (EPP); 1984 (EPP), 1986 (EPP); 1989 (EPP); 1991 (RE); 1992 (EPP), 1993 (EPP); 1995 (EPP); 2258 (S&D)

Fall: AMs 1980 (S&D); 1983 (ID); 1985 (ID); 1987 (ID), 1988 (Greens); 1990 (ID); 1994 (ID);

~~Parked: 1992 (EPP)) linked to governance;~~

Article 25
Authorised representatives

1. Prior to making their systems available on the Union market, ~~where an importer cannot be identified,~~ ***(AMs 123, 1981, 1982)*** providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

2. The authorised representative shall reside or be established in one of the Member States where the activities pursuant to Article 2, paragraphs 1(cb)~~(b) and (c)1a~~, are taking place. (AM 2258)

3. The provider shall provide its authorised representative with the necessary powers and resources to comply with its tasks under this Regulation. (AM 2258)

4. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***It shall provide a copy of the mandate to the market surveillance authorities upon request, in an official Union language determined by the national competent authority. (AM 124) For the purpose of this Regulation (AM 1984), ~~T~~t***he mandate shall empower the authorised representative to carry out the following tasks:

(a) ***ensure that ~~keep a copy of~~*** the EU declaration of conformity and the technical documentation ***have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider (AM 1986)***; ~~***at the disposal of the national competent authorities and national authorities referred to in Article 63(7);***~~

(aa) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body; (AM 1989)

(b) provide a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider ~~by virtue of a contractual arrangement with the user or otherwise by law~~;

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(c) cooperate with ***national supervisory authorities (AMs 125, 1992)*** ~~competent national authorities~~, upon a reasoned request, on any action the ~~latter~~ ***authority*** takes ***to reduce and mitigate the risks posed by the ~~in relation to the~~ (AM 1991)*** high-risk AI system.

(ca) where applicable, comply with the registration obligations referred in Article 51, (AM 126) or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of Annex VIII is correct. (AM 1993)

5. The authorised representative shall be mandated to be addressed, in addition to or instead of the provider, by, in particular, national supervisory authority or the national competent authorities, on all issues related to ensuring compliance with this Regulation. (AM 2258)

6. The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the national supervisory authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof. (AM 1995)

COMP AM 3ia on matching recitals to Article 25

Covering AMs: 56 (Rapp); 662 (RE)

Falls: 661 (S&D)

~~Parked: 661 (S&D) - legal representative;~~

(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~~, ***(AM 56, 662)*** providers established outside the Union shall, by written mandate, appoint an authorised representative established in the Union.

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COMP AM 3j

Covering AMs 127 (Rapp); 128 (Rapp); 1996 (EPP); 1998 (EPP); 1999 (EPP); 2000 (EPP); 2001 (EPP); 2002 (Greens); 2004 (S&D), 2008 (EPP)

Fall: AMs 1997 (ID); 2003 (EPP); 2005 (Greens); 2006 (EPP); 2007 (ID);

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Article 26
Obligations of importers

1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by ensuring that (AM 1996)***:

   (a) the ~~***appropriate***~~ ***relevant (AM 1998)*** conformity assessment procedure ***referred to in Article 43 (AM 1998)*** has been carried out by the provider of that AI system

   (b) the provider has drawn up the technical documentation in accordance with ***Article 11 and (AM 127)*** Annex IV;

   (c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use***; (AM 1999)***

   (ca) where applicable, the provider has appointed an authorised representative in accordance with Article 25(1). (AM 128, 2000)

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, ***or is counterfeit, or accompanied by falsified documentation (AM 2001)*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system ~~***or where that is not possible***~~ ***and (AM 2002)*** on its packaging or its accompanying documentation, ***where (AM 2002)***applicable.

4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title.

5. Importers shall provide national competent authorities, upon a reasoned request, with all ***the (AM 2004)*** necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by ***them*** ~~***that national competent authority***~~, ***(AM 2004)*** including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider ***in accordance with Article 20.*** ~~by virtue of a contractual arrangement~~

~~with the user or otherwise by law.~~ ~~***They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.***~~

5 a. Importers shall cooperate with national competent authorities on any action those authorities take to reduce and mitigate the risks posed by the high-risk AI system. (AM 2008)

COMP AM 3k

Covering AMs 129 (Rapp); 130 (Rapp); 2009 (EPP); 2010 (EPP); 2013 (Greens), 2014 (EPP); 2015 (RE); 2018 (RE), 2019 (RE); 2022 (EPP)

Fall: AMs 2011 (RE); 2012 (RE); 2016 (ID); 2017 (Greens), 2018 (RE); 2020 (EPP); 2021 (Greens)

~~Parked: 2017 (Greens) and 2021 (Greens) - governance;~~

Article 27
Obligations of distributors

1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the***ir*** obligations set out in this Regulation ***in Article 16 and Article 26 respectively.(AM 2009)***

2. Where a distributor considers or has reason to consider***, on the basis of the information in its possession (AM 2010)*** that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, ***~~and~~ the relevant national competent authority***, ***(AM 129, 2013)*** as applicable, to that effect

3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of this Title.

4. A distributor that considers or has reason to consider, ***on the basis of the information in its possession, (AMs 2014, 2015)*** that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform ***the provider or importer of the system and (AMs 2014, 2015)*** the national competent authorities of

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the Member States in which it has made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective actions taken.

5. Upon a reasoned request from a national competent authority, distributors of ***the (AM 130)*** high-risk AI systems shall provide that authority with all the information and documentation ***in their ~~its~~ possession or available to them, in accordance with the obligations of distributors as outlined in paragraph 1, that are (AM 2018, 2019)*** necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. ~~***Distributors shall also cooperate with that national competent authority on any action taken by that authority***~~.

5a. Distributors shall cooperate with national competent authorities on any action those authorities take to reduce and mitigate the risks posed by the high-risk AI system. (AM 2022)

COMP AM 3ka on matching recitals to Articles 26 and 27

Covering AMs: /

Falls: /

(57) In line with New Legislative Framework principles, specific obligations for relevant economic operators, such as importers and distributors, should be set to ensure legal certainty and facilitate regulatory compliance by those relevant operators

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COMP AM 31

Article 28

Obligations of distributors, importers, users or any other third-party

1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

   (a) they place on the market or put into service a high-risk AI system under their name or trademark;

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

   (c) they make a substantial modification to the high-risk AI system.

2. Where the circumstances referred to in paragraph 1, point (b) or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation.

The developers of free and open-source AI components shall not be mandated to comply with such obligations towards the provider that has integrated the free and open-source AI component in his or her high-risk AI system.

Recitals: ***Software and data that are openly shared and where users can freely access, use, modify and redistribute them or modified versions thereof, can contribute to research and innovation in the market. Research by the European Commission also shows that free and open-source software can contribute between €65 billion to €95 billion to the European Union's GDP and that it can provide significant growth opportunities for the European economy. Users are allowed to run, copy, distribute, study, change and improve software and data, including models by way of free and open-source licences. To foster the development and deployment of AI, especially by SMEs, start-ups, academic research but also by individuals, this Regulation should not apply to such free and open-source AI components except to the extent that they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV of this Regulation.***

Neither the collaborative development of free and open-source AI components nor making them available on open repositories should constitute a placing on the market or putting into service. A commercial activity, within the understanding of making available on the market, might however be characterised by charging a price, with the exception of transactions between micro enterprises, for a free and open-source AI component but also by charging a price for technical support services, by providing a software platform through which the provider monetises other services, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software.

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The developers of free and open-source AI components should not be mandated under this Regulation to comply with requirements targeting the AI value chain and, in particular, not towards the provider that has used that free and open-source AI component. Developers of free and open-source AI components should however be encouraged to implement widely adopted documentation practices, such as model and data cards, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the EU.

Article 29

*Obligations of ~~users~~ **deployers** of high-risk AI systems*

1. ~~Users~~ ***Deployers*** of high-risk AI systems shall ***take appropriate technical and organisational measures to ensure they (AM 2038)*** use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5 ***of this Article***.

1a To the extent deployers exercise control over the high-risk AI system, they shall

implement human oversight according to the requirements laid down in this Regulation (AM 136, 2037, 2039, 2040) and

ensure that the natural persons assigned to ensure human oversight of the high-risk AI systems are competent, properly qualified and trained, and have the necessary resources in order to ensure the effective supervision of the AI system in accordance with Article 14 (AM 137, 138, 2036, 2042, 2044, 2045)

. ~~Users~~ ***ensure that relevant and appropriate robustness and cybersecurity measures are regularly monitored for effectiveness and are regularly adjusted or updated (AM 2042, 2049, 2050)***

2. The obligations in paragraph 1, ***1a, 1b and 1c (AM 139, 2048)*** are without prejudice to other ~~users~~ ***deployer*** obligations under Union or national law and to the ~~users~~ ***deployer's*** discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

3. Without prejudice to paragraph 1, ***1a, 1b and 1c (AM 140)***, to the extent the ~~users~~ ***deployer*** exercises control over the input data, that ~~users~~ ***deployer*** shall ensure that input data is relevant ***and sufficiently representative (AM 2051)*** in view of the intended purpose of the high-risk AI system.

4. ~~Users~~ ***Deployers*** shall monitor the operation of the high-risk AI system on the basis of the instructions of use ***and when relevant, inform providers in accordance with Article 61.*** When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall, ~~***immidiately***~~ ***without undue delay,*** inform the provider or distributor ***and relevant national supervisory authority (AM 2053, 2055, 2056)*** and suspend the use of the system. They shall also ***immediately (AM 141, 2056)*** inform ***first*** the provider***, and then the importer (AMs 2953, 2054)*** or distributor ***and relevant national supervisory authority (AM 2053, 2055)*** when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and

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

For ~~users~~ ***deployers*** that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

5. ~~Users~~ ***Deployers*** of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent ***that*** such logs are under their control ***and are required for ensuring and demonstrating compliance with this Regulation, for ex-post audits of any reasonably foreseeable malfunction, incidents or misuses of the system, or for ensuring and monitoring for the proper functioning of the system throughout its lifecycle (AM 142)***. ***Without prejudice to applicable Union or national law,*** the logs shall be kept for a period ***of at least 6 months. The retention period shall be in accordance with industry standards and*** appropriate ***to*** the intended purpose of the high-risk AI system ~~and applicable legal obligations under Union or national law~~. ***(AMs 2058, 2059)***

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

5a Prior to putting into service or use a high-risk AI system at the workplace, ~~users~~ deployers shall consult workers representatives with a view to reaching an agreement in accordance with Directive 2002/14/EC and inform the affected employees that they will be subject to the system ~~and obtain their consent~~ (AM 2060)

5b. ~~Users~~ Deployers of high-risk AI systems that are public authorities or Union institutions, bodies, offices and agencies or undertakings referred to in Article 51(1a)(b) shall comply with the registration obligations referred to in Article 51 (AM 143, 2063).

6. ***Where applicable,*** ~~users~~ ***deployers*** of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680***, a summary of which shall be published (2066)***, ~~***where applicable***~~ ***having regard to ~~the technical characteristics of the system~~ the specific use and the specific context in which the AI system is intended to operate (AM 144). Deployers may revert in part to those data protection impact assessments for fulfilling some of the obligations set out in this article, insofar as the data protection impact assesment fulfill those obligations (AM 2064, 2065).***

~~***6 a. The provider shall be obliged to cooperate closely with the deployer and in particular provide the deployer with the necessary information to allow the fulfilment of the obligations set out in this Article (AM 2074)***~~

6a. ~~Users~~ Without prejudice to Article 52, deployers of high-risk AI systems referred to in Annex III, which make decisions or assist in making decisions related to natural persons, shall inform the natural persons that they are subject to the use of the

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high-risk AI system. This information shall include ~~the type of high-risk systems used and its~~ the intended purpose and the type of decisions it makes (AM 145, 2072). The deployer shall also inform the natural person about its right to an explanation referred to in Article 68c.

6b. ~~Users~~ Deployers of AI systems that generate, on the basis of limited human input, complex text content, such as news articles, opinion articles, novels, scripts and scientific articles, shall disclose that the text content has been artificially generated or manipulated, including to the natural persons who are exposed to the content, in a clear and intelligible manner (AM 146), with the exception of content that undergoes human review and for the publication of which a natural or legal person is liable or holds editorial responsibility.

7. ~~Users~~ Deployers shall cooperate with the relevant national competent authorities on any action those authorities take in relation with the high-risk system in order to implement this Regulation (AM 2077)

Article 29a

Fundamental rights impact assessment for high-risk AI systems

1. Prior to putting a high-risk AI system as defined in Article 6(2) into use, with the exception of AI systems intended to be used in area 2 of Annex III, ~~users~~ deployers shall conduct an assessment of the systems' impact in the specific context of use, ~~irrespective of whether such obligation is indicated in the instructions of use~~.. This assessment shall include, at a minimum, the following elements:

(a) a clear outline of the intended purpose for which the system will be used;

(b)a clear outline of the intended geographic and temporal scope of the system's use;

(ba) categories of natural persons and groups likely to be affected by the use of the system;

(c) verification that the use of the system is compliant with relevant Union and national law on ~~and with~~ fundamental rights ~~law~~;

(d) the reasonably foreseeable ~~direct or indirect~~ impact on fundamental rights of putting the high-risk AI system into use;

(e) specific risks of harm likely to impact marginalised persons or vulnerable groups;

(f) the reasonably foreseeable adverse impact of the use of the system on the environment; ~~including but not limited to energy consumption;~~

~~(g) any other negative impact on the protection of the values enshrined in Article 2 TEU;~~

~~(h) in the case of public authorities, any other impact on democracy, rule of law and allocation of public funds; and~~

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(i) a detailed plan as to how the harms and the negative ~~direct or indirect~~ impact on fundamental rights identified will be mitigated.

(j) the governance system the deployer will put in place, including human oversight, complaint-handling and redress. (AM 1671)

2. *If a detailed plan to mitigate the risks outlined in the course of the assessment outlined in paragraph 1 cannot be identified, the ~~user~~ deployer shall refrain from putting the high-risk AI system into use and inform the provider and the ~~relevant~~ National ~~competent~~ supervisory authority without undue delay. ~~Market surveillance~~ National supervisory authorities, pursuant to Articles 65 and 67, shall take this information into account when investigating systems which present a risk at national level.*

3. *The obligation outlined under paragraph 1 applies for ~~each new~~ the first use of the high-risk AI system. The deployer may, in similar cases, draw back on previously conducted fundamental rights impact assessment or existing assessment carried out by providers. If, during the use of the high-risk AI system, the deployer considers that the criteria listed in paragraph 1 are no longer met, it shall conduct a new fundamental rights impact assessment.*

4. *In the course of the impact assessment, the ~~user~~ deployer, with the exception of SMEs, shall notify ~~relevant~~ national ~~competent authorities~~ supervisory authority and relevant stakeholders and shall, to best extent possible, involve representatives of the persons or groups of persons that are ~~reasonably foreseeable~~ likely to be affected by the high-risk AI system, as identified in paragraph 1, including but not limited to: equality bodies, consumer protection agencies, social partners and data protection agencies, with a view to receiving input into the impact assessment. The ~~user~~ deployer must allow a period of six weeks for bodies to respond. SMEs may voluntarily apply the provisions laid down in this paragraph.*

In the case referred to in Article 47(1), public authorities may be exempted from this obligations.

4. *The ~~user~~ deployer that is a public authority or an undertaking referred to in Article 51(1a)(b) shall publish a summary of the results of the impact assessment as part of the registration of use pursuant to their obligation under Article 51(2). (AMs 2078, 2079, 2080, 2081, 2082, 2083, 2085)*

5. *Where the deployer is already required to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 shall be conducted in conjunction with the data protection impact assessment. The data protection impact assessment shall be published as an addendum.*

RECITAL

Covers: AMs 663 (RE); 665 (Greens); 666 (S&D); 667 (Greens); 668 (S&D);

Obtenu par COMTEXTE

Falls: 664 (ID)

RECITAL

Covers: AMs 663 (RE); 665 (Greens); 666 (S&D); 667 (Greens); 668 (S&D);

Falls: 664 (ID)

(58) Given the nature of AI systems and the risks to safety and fundamental rights possibly associated with their use, including as regard***s (AM 665)*** 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~~ ***deployers***. ~~Users~~ ***Deployers (AM 665)*** 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 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. Deployers 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. Deployers are best placed to understand how the high-risk AI system will be used concretely and can therefore identify potential significant 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 deployer 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 mitigate the risks to fundamental rights identified and, if such plan cannot be identified, the deployer should refrain from putting the system into use. When performing this impact assessment, the deployer should notify the national supervisory authority, as well as relevant stakeholders and civil society. 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, with the exception of SMEs which, given the lack of resources, might find it difficult to do it. Nevertheless, they should also strive to involve such representatives when carrying out their fundamental rights impact assessment.***

AI ACT - COMPROMISE AMENDEMENTS

BATCH 1 - FINAL VERSION - 19.04.2023

Obtenu par CONTEXTE

CHAPTER 4: NOTIFIYING AUTHORITIES AND NOTIFIED BODIES

COMP AM 4a

Covering: AMs 147 (Rapp), 148 (Rapp), 149 (Rapp), 150 (Rapp), 152 (Rapp), 153 (Rapp), 154 (Rapp), 155 (Rapp), 156 (Rapp), 157 (Rapp), 158 (Rapp), 159 (Rapp), 2086 (EPP), 2087 (EPP), 2089 (greens), 2090 (EPP), 2092 (S&D), , 2095 (EPP), 2096 (S&D), 2098 (S&D), 2100 (S&D), 2101 (ECR), 2102 (EPP), 2103 (Greens), 2104 (S&D), 2105 (ECR), 2109 (EPP), 2110 (S&D), 2112 (S&D), 2116 (EPP), ~~2119 (S&D)~~

Fall: AMs 151 (Rapp), 2088 (The Left), 2091 (ID); 2093 (EPP), 2094 (S&D)2097 (EPP); 2099 (ID), 2016 (ID), 2107 (EPP), 2108 (ID), 2111 (Greens), 2113 (Greens), 2114 (ID), 2115 (The Left), 2117 (ID), 2119 (S&D)

Article 30
Notifying authorities

1. Each Member State shall designate or establish a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. ***These procedures shall be developed in cooperation between the notifying authorities of all Member States (AM 2086).***

2. Member States may designate a national accreditation body referred to in Regulation (EC) No 765/2008 as a notifying authority.

3. Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.

4. Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.

5. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.

6. Notifying authorities shall safeguard the confidentiality of the information they obtain.

7. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks. ***Where applicable, competent personnel shall have the necessary expertise, such as a degree in an appropriate legal field, in supervision of fundamental rights enshrined in the Charter of Fundamental rights of the Union (AM 2089).***

8. Notifying authorities shall make sure that conformity assessments are carried out in a proportionate ***and timely (AM 2092)*** manner, avoiding unnecessary burdens for providers**,** and that notified bodies perform their activities taking due account of the

Obtenu par CONTEXTE

size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question. ***Particular attention shall be paid to minimising administrative burdens and compliance costs for micro and small enterprises as defined in Commission Recommendation 2003/361/EC (AM 2090).***

Article 31

Application of a conformity assessment body for notification

1. Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 33. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 33. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate.

Article 32

Notification procedure

1. Notifying authorities ~~may~~ ***shall (AM 148, 2095)*** notify only conformity assessment bodies which have satisfied the requirements laid down in Article 33.

2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission ***of each conformity assessment body referred to in paragraph 1***. ***(AM 149)***

3. The notification ***referred to in paragraph 2 (AM 150)*** shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned***, as well as the relevant attestation of competence (AM 2096)***.

4. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within ~~one month of a~~ ***two weeks of the validation of the*** notification ***where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it incudes documentary evidence referred to in Article 31(3 (AM 2098)***.

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4a. Where objections are raised, the Commission shall without delay enter into consultation with the relevant Member States and the conformity assessment body. In view thereof, the Commission shall decide whether the authorisation is justified or not. The Commission shall address its decision to the Member State concerned and the relevant conformity assessment body (AM 2100).

4b. Member States shall notify the Commission and the other Member States of conformity assessment bodies. (AM 147)

5. Notifying authorities shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 33
Notified bodies

1. Notified bodies shall verify the conformity of high-risk AI system in accordance with the conformity assessment procedures referred to in Article 43.

2. Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks ***as well as the minimum cybersecurity requirements set out for public administration entities identified as operators of essential services pursuant to Directive XXX on measures for a high common level of cybersecurity across the Union (NIS2), repealing Directive (EU) 2016/1148 (AM 2101, 2102)***.

3. The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall be such as to ensure that there is confidence in the performance by and in the results of the conformity assessment activities that the notified bodies conduct.

4. Notified bodies shall be independent of the provider of a high-risk AI system in relation to which it performs conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in the high-risk AI system that is assessed, as well as of any competitors of the provider. ***This shall not preclude the use of assessed AI systems that are necessary for the operations of the conformity assessment body or the use of such systems for personal purposes (AM 2104).***

4a. Conformity assessment pursuant to paragraph 1 shall be performed by employes of notified bodies who have not provided any other other service related to the matter assessed than the conformity assessment to the provider of a high-risk AI system nor to any legal person connected to that provider in the 12 months' period before the assessment and have committed to not providing them with such services in the 12 months' period after the completion of the assessment. (AM 2103)

5. Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.

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6. Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out. ***Any information and documentation obtained by notified bodies pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70 (AM 2105).***

7. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the AI system in question.

8. Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State concerned in accordance with national law or that Member State is directly responsible for the conformity assessment.

9. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

10. Notified bodies shall have sufficient internal competences to be able to effectively evaluate the tasks conducted by external parties on their behalf. To that end, at all times and for each conformity assessment procedure and each type of high-risk AI system in relation to which they have been designated, the notified body shall have permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant artificial intelligence technologies, data and data computing and to the requirements set out in Chapter 2 of this Title.

11. Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly or be represented in European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.

12. Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 30 to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.

Obtenu par CONTEXTE

Article 34

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 33 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider. ***Notified bodies shall make a list of their subsidiaries publicly available. (AM 152)***

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the ~~assessment~~ ***verification (AM 153, 2109)*** of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 35

*Identification numbers and lists of notified bodies ~~designated under this Regulation~~ **(AM 154)***

1. The Commission shall assign an identification number to notified bodies. It shall assign a single number, even where a body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.

Article 36

Changes to notifications

1. Where a notifying authority has suspicions or has been informed that a notified body no longer meets the requirements laid down in Article 33, or that it is failing to fulfil its obligations, that authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body ~~investigation~~ ***(AM 2110)*** no longer meets the requirements laid down in Article 33 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure. It shall also immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that notified body are either taken over by another

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notified body or kept available for the responsible notifying authorities***, and market surveillance authority (AM 155)*** at their request.

Article 37
Challenge to the competence of notified bodies

1. The Commission shall, where necessary ~~***(AM 156, 2111),***~~ investigate all cases where there are reasons to doubt ~~whether~~ ***the competence of*** a notified body ***or the continued fulfilment by a notified body of the applicable*** ~~complies with the~~ requirements ~~laid down in Article 33~~ ***and responsibilities***. ***(AM 156)***

2. The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification ***or the maintenance of the competence (AM 157)*** of the notified body concerned.

3. The Commission shall ensure that all ~~confidential~~ ***sensitive (AM 2112)*** information obtained in the course of its investigations pursuant to this Article is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements ***for its notification***, ~~laid down in Article 33~~,***(AM 158)*** it shall ~~adopt a reasoned decision~~ ~~***an implementing act (AM 158)***~~ ~~requesting~~ ***inform*** the notifying Member State ***accordingly and request it*** to take the necessary corrective measures, including ***suspension or*** withdrawal of ***the*** notification if necessary. ***Where the Member State fails to take the necessary corrective measures, the Commission may, by means of an implementing act, suspend, restrict or withdraw the designation.*** That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Article 38
Coordination of notified bodies

1. The Commission shall ensure that, with regard to the areas covered by this Regulation, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures of AI systems pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies**.**

2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

3a. The Commission shall provide for the exchange of knowledge (AM 2116) and best practices between the Member States' national authorities responsible for notification policy. (AM 159)

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Article 39
Conformity assessment bodies of third countries

Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement ***~~also covering this respect (AM 2119)~~*** may be authorised to carry out the activities of notified Bodies under this Regulation.

COMP AM 4aa

Covering AMs 687 (EPP), 688 (RE), 689 (S&D), 2118 (EPP), 2120 (EPP), 2121 (EPP)

Fall: AM 686 (Greens).

(65) In order to carry out third-party conformity assessments ***when so required*** ~~for AI systems intended to be used for the remote biometric identification of persons~~ ***(AM 688, 689)***, 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 and minimum cybersecurity requirements (687)***. ***Member States should encourage the designation of a sufficient number of conformity assessment bodies, in order to make the certification feasible in a timely manner (AM 2087). The procedures of assessment, designation, notification and monitoring of conformity assessment bodies should ~~result in standard procedures~~ be implemented ~~equally~~ as uniformly as possible in ~~al~~ Member States, with a view to removing administrative border barriers and ensuring that the potential of the internal market is realised (AM 2086 2nd part).***

(65a) In ~~accordance~~ line with Union ~~EU~~ commitments under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT), ~~the Commission should endeavour~~ it is adequate to maximise the acceptance of test results produced by competent conformity assessment bodies, independent of the territory in which they are established, where necessary to demonstrate conformity with the applicable requirements of the Regulation. ~~Conformity assessment bodies established under the law of a third country are able tocan carry out the activities of notified bodies under this Rregulation where they have been accredited as competent by an accreditation body, whether established in the territory of the UnionEU or a third country, that is a signatory of an international accreditation or conformity assessment scheme based on rigorous peer-review processes, such as the International Laboratory Accreditation Collaboration (ILAC) Mutual Recognition Arrangement (MRA), and the International Accreditation Forum (IAF) or the Multilateral Recognition Arrangement (MLA).~~ The Commission should actively explore possible international instruments for that purpose and in particular pursue the possible establishment of mutual recognition agreements with countries which are on a comparable level of technical development, and have compatible approach concerning AI and conformity assessment. ~~In addition, where conformity assessment bodies established under the law of a third country have not been

Obtenu par COMITEXTE

~~*accredited by signatory bodies of such international accreditation or conformity assessment schemes, third-country conformity assessment bodies are able tocan carry out the activities of notified bodies where international mutual recognition arrangements, conformity assessment protocols, or other agreements exist between the UnionEU and the country in which the conformity assessment body is established*~~ *(AM 2118, 2120, 2121).*

AI ACT - COMPROMISE AMENDEMENTS - BATCH 2 - V5-11.02.2023
Chapter 5: Standards, conformity assessment, certificates, registration

COMP AM 5a
Covering: AMs 160 (Rapp), 2122 (EPP), 2124 (EPP), 2125 (Renew), ~~2126 (The Left),~~ ~~2127 (S&D),~~ 2128 (EPP), TRAN 94, ITRE 55, ITRE 56, ***3008 (RE), 3009 (EPP)***
Fall: AM 2123 (ID), ITRE 57, ITRE 58

Article 40
Harmonised standards

1. High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union ***in accordance with Regulation 1025/2012 (AM 2122)*** shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.

Technical specifications exclusively related to fundamental rights shall be developed in accordance with Article 41.

1a. The Commission shall issue standardisation requests covering all requirements of this Regulation, with the exception of technical specifications exclusively related to fundamental rights, in accordance with Article 10 of Regulation 1025/2012 no later than 2 months after the date of entry into force of this Regulation (AM 2125, 2128, 3008, 3009).

1b. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards shall be coherent, including with sectorial legislation listed in Annex II, ~~easy to implement~~ and aimed at ensuring that AI systems placed on the market or put into service in the Union meet the relevant requirements ~~and obligations~~ laid down in this Regulation (AM 2124, TRAN 94)

1c. The standardisation process shall take into account the general principles for trustworthy AI set out in Article 4(a), promote investment and innovation in AI as well as competitiveness and growth of the Union market, contribute to strengthening global cooperation on standardisation in the field of AI that is consistent with Union values, fundamental rights and interests (AM 2124, ITRE 55), and ensure a balanced

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representation of interests and effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012 (AM 160, ITRE 56).

COMP AM 5b
Covering: AMs 161 (Rapp), 2130 (EPP), 2131 (Renew), 2133 (Renew), 2136 (Greens), 2138 (Renew), ~~2139 (Renew)~~, 2140 (EPP), ~~2141 (Renew),~~ 2143 (EPP), 2144 (EPP), 2146 (EPP), 2148 (EPP), 2149 (Renew), 2150 (Renew), ~~CULT 50,~~ TRAN 95, TRAN 96, ~~ITRE 60~~
Fall: AMs 2129 (ECR), 2132 (TheLeft), 2134 (EPP), 2135 (ID), 2137 (EPP), 2139 (RE), ~~2140 (EPP~~), 2141 (RE), 2142 (ID), 2145 (ID), 2147 (ID), ITRE 59, ITRE 60, CULT 50

Article 41
Common specifications

1. ~~Where one of the following condition is met:~~

a) ~~harmonised standards referred to in Article 40 do not exist~~

b) ~~harmonised standards *are not expected to be published within a reasonable period (AM 2133)*~~

c) ~~the Commission considers that the relevant harmonised standards are insufficient~~

d) ~~the Commission has concluded that the relevant harmonised standards *do not satisfy the requirements in accordance with Regulation 1025/2012 (AM 2130)*~~

e) ~~the Commission considers that there is a need to address specific safety *or accessibility (AM 2136) or fundamental right* concerns,~~

~~the Commission *shall issue a standardisation request to one or several of the European standardization organisations in accordance with Article 10 of Regulation 1025/2012 (AM 2131).*~~

1a~~b~~. ***When there are undue delays in the standardisation procedure or if ~~when~~ the standardisation request referred to in Article 40 ~~paragraph 1~~ has, without justification ~~reason,~~ not been accepted by the European standardisation organisations concerned (AM 2130), the Commission*** may, by means of implementing acts, ***and after consulting the AI office (AM 2130, TRAN 95)***, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title, Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

~~*1c. Insofar as fundamental rights are concerned, the Commission may by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title, where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific fundamental right concerns.*~~

1b. Irrespective of paragraph 1a, the Commission shall by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 exclusively related to fundamental rights.

Obtenu par CONTEXTE

2. The Commission, ***throughout the whole process of drafting*** ~~***when preparing***~~ the common specifications referred to in paragraph***s 1a and 1b*** ~~***1***~~, shall ~~***gather the views of***~~ ***regularly consult (AM 2143) the AI office and the advisory forum*** ~~***Board***~~***,*** ~~***the Committee referred to in Article 22 of Regulation 1025/2012 (AM 2130),***~~ ***the European standardisation organisations and*** bodies or expert groups established under relevant sectorial Union law ***as well as other relevant stakeholders (AM 161),*** ~~***including industry, start-ups and SMEs, start-ups, civil society, researchers and social partners (AM 2139, 2141, 2143, 2144, CULT 50, TRAN 96, ITRE 60),***~~ ~~bodies or expert groups established under relevant sectorial Union law~~. ***The Commission shall fulfil the objectives referred to in Article 40 and (AM 2140) duly justify why it decided to resort to common specifications*** ~~***not to use harmonised standards***~~ ***(2138).***

3. High-risk AI systems which are in conformity with the common specifications referred to in paragraph ***1a and 1b*** ~~***1b and 1c***~~ shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those common specifications cover those requirements.

3a When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal implementing acts referred to in paragraph 1b, or parts thereof which cover the same requirements set out in Chapter 2 of this Title.

4. Where providers ***of high-risk AI systems (AM 2149)*** do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that ***meet the requirements referred to in Chapter II to a level (AM 2148)*** ~~***are***~~ at least equivalent thereto.

COMP AM 5ab on matching recitals to Articles 40 and 41:
Covering: AM 33 (Rapp), AM 674 (Renew), AM 675 (EPP), AM 677 (EPP), AM 2124 (EPP), 2126 (The Left), 2127 (S&D), ITRE 11
Falls: AM 673 (ID), AM 676 (Greens)
~~Parked: ITRE 11~~

(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[19] should be a means for providers to demonstrate conformity with the requirements of this Regulation. ~~***However,***~~ ***To ensure the effectiveness of standards*** ~~***and standardisation***~~ ***as policy tools for the Union and considering the the importance of standards for the competitiveness of undertakings and for ensuring conformity with the requirements of this Regulation, it is necessary to ensure a***

[19] 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).

Obtenu par CONTEXTE

balanced representation of interests by ~~encouraging the participation of~~ involving all relevant stakeholders in the development of standards (AM 33). The standardisation process should be transparent in terms of legal and natural persons participating in the standardisation activities (ITRE 11)

(61b) In order to facilitate compliance, the first standardisation requests should be issued by the Commission ~~prior to the entry into force of this Regulation or~~ two months after ~~it~~ the entry into force of this Regulation at the latest. This should serve to improve legal certainty, thereby ~~The requests should be aimed at~~ promoting investment and innovation in AI, as well as competitiveness and growth of the Union market, while ~~at~~ enhancing multistakeholder governance representing all relevant European stakeholders such as the AI office ~~Board, the Committee referred to in Article 22 of Regulation 1025/2012,~~ European standardisation organisations and bodies or experts groups established under relevant sectorial Union law as well as industry, SMEs, start-ups, civil society, researchers and social partners, and should ultimately ~~be oriented at strengthening~~ facilitate global cooperation on standardisation in the field of AI in a manner consistent with Union values (AM 2124).

(61c) When AI systems are intended to be used ~~deployed~~ at the workplace, harmonised standards should be limited to technical specifications and procedures (AM 2126, 2127).

(61d) The Commission ~~*could*~~ *may (AM 675)* adopt common ~~technical~~ specifications ~~in areas where no harmonised standards exist~~ *when there are undue delays in the standardisation procedure or if the standardisation request has not been accepted by any of the European standardisation organisation without justification. ~~or they are not expected to be published within a reasonable period (AM 674) or where~~* ~~they are insufficient,~~ *~~they do not satisfy the requirements in accordance with Regulation 1025/2021 or there is a need to address specific safety or accessibility concerns.~~ In addition, the Commission may adopt common specifications in respect of the requirements set out in Chapter 2 exclusively related to fundamental rights . In both cases, such common specifications should be adopted only after consulting the Artificial intelligence Office ~~board~~. Through the whole drafting process, the Commission should regularly consult the AI Office and its advisory forum, the European standardisation organisations and bodies or expert groups established under relevant sectorial Union law as well as relevant stakeholders, such as industry, SMEs, start-ups, civil society, researchers and social partners.*

(61e) When adopting common ~~technical~~ specifications, the Commission should strive ~~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, as Coordination with likeminded partners in international standardisation bodies is ~~therefore~~ of great importance (AM 677).

Obtained CONFIDENCE

Obtenu par CONTEXTE

COMP AM 5c
Covering: ~~***AMs 2152 (Greens),***~~ 2154 (EPP), 2153 (TheLeft), ITRE 61, ITRE 62,
Fall: AMs 2151 (TheLeft), ***2152 (Greens),*** ~~2153 (TheLeft),~~ 2155 (EPP)

Article 42
Presumption of conformity with certain requirements

1. Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural, ***contextual (ITRE 61***) and functional setting within which they are intended to be used ~~***or are reasonably foreseeable to be used (AM 2152)***~~ shall be presumed to be in compliance with the ***respective*** requirement***s (AM 2154)*** set out in Article 10(4).

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council[20] and the references of which have been published in the Official Journal of the European Union shall be presumed to be in compliance with the cybersecurity requirements set out in Article 15, ~~***where applicable (ITRE 62)***~~ of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

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20 Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

COMP AM 5d

Covering: 2157 (Left), 2158 (ID), 2159 (S&D), 2160 (Greens), 2161 (EPP), 2166 (EPP), 2171 (EPP), 2177 (Greens), 2178 (S&D), 2179 (S&D), 2191 (RE), ***2192 (Greens),*** 2197 (S&D), 2198 (EPP), 2200 (EPP), 2201 (RE), ***ITRE 64, ITRE 65***

Falls: 2156 (Greens), 2162 (ID), 2163 (Left), 2164 (S&D), 2165 (Greens), 2167 (ID), 2168 (S&D), 2169 (Greens), 2170 (Left), 2172 (Greens), 2173 (S&D), 2174 (ID), 2175 (RE), 2176 (S&D), 2180 (Left), 2181 (Greens), 2182 (S&D), 2184 (ID), 2186 (Greens), 2187 (ID), 2188 (EPP), 2189 (RE), 2190 (EPP), ***2193 (RE),*** 2194 (Left), 2195 (ID***), 2196 (EPP***), 2199 (EPP), 2202 (ID), 2203 (ID), 2204 (Greens), 2205 (S&D), 2206 (EPP), 2207 (EPP), 2208 (RE), ***ENVI 82, ENVI 83, TRAN 97, ITRE 63***

~~***Parked: 2192 (Greens)- deployer, 2193 (RE) and 2196 (EPP)***~~

Article 43
Conformity assessment

1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~***follow***~~ ***opt for (AM 2161)*** one of the following procedures:

   (a) the conformity assessment procedure based on internal control referred to in Annex VI; ***or (AM 2166)***

   (b) the conformity assessment procedure based on assessment of the quality management system and ~~***assessment***~~ ***(AM 2171)*** of the technical documentation, with the involvement of a notified body, referred to in Annex VII.

   ~~***Where,***~~ ***In*** demonstrating the compliance of a high-risk AI system with the requirements set out in Chapter 2 of this Title, the provider ~~***the provider***~~ ***shall follow the conformity assessment procedure set out in Annex VII in the following cases:***

   (a) where harmonised standards referred to in Article 40, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the AI system, do not exist and common specifications referred to in Article 41 are not available;

   (b) where the technical specifications referred to in point (a) exist but the provider has not applied them or has applied them only in part;

   (c) where one or more of the technical specifications referred to in point (a) has been published with a restriction (AM 2179) and only on the part of the standard that was restricted;

   (d) when the provider considers that the nature, design, construction or purpose of the AI system necessitate third party verification, regardless of its risk level (AM 2179, 2198).

Obtenu par CONTEXTE

~~***has not applied or has applied only in part harmonised standards referred to in Article 40, or where such harmonised standards do not exist and common specifications referred to in Article 41 are not available, the provider shall follow the conformity assessment procedure set out in Annex VII.***~~

For the purpose of ***carrying out (AM 2177)*** the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, when the system is intended to be put into service by law enforcement, immigration or asylum authorities as well as EU institutions, bodies or agencies, the market surveillance authority referred to in Article 63(5) or (6), as applicable, shall act as a notified body.

2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body. For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive.

3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.

   For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.

   Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title.

4. High-risk AI systems ***that have already been subject to a conformity assessment procedure (AM 2191)*** shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current ~~***user***~~ ***deployer.***

   For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity

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assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.

4 a. ***The specific interests and needs of ~~the~~ ~~small scale providers~~ SMEs shall be taken into account when setting the fees for third-party conformity assessment under this Article, reducing those fees proportionately to their size and market share (AM 2197).***

5. The Commission is empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating Annexes VI and Annex VII in order to introduce elements of the conformity assessment procedures that become necessary in light of technical progress. ***In doing so, the Commission shall consult the AI Office and the affected stakeholders (AM 2200, 2201, ITRE 64)***

6. The Commission is empowered to adopt delegated acts to amend paragraphs 1 and 2 in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimizing the risks to health and safety and protection of fundamental rights posed by such systems as well as the availability of adequate capacities and resources among notified bodies. ***In doing so, the Commission shall consult the AI Office and the affected stakeholders (ITRE 65).***

COMP AM 5dd on matching recitals
Covering: /
Falls: AMs 679 (Greens), 680 (ID), 681 (S&D), 682 (ID), 683 (RE), 684 (Greens), 685 (EPP), 691 (EPP), 692 (ID), 694 (Greens), ***695 (TheLeft), 696 (EPP)***
Parked: AM 678 (EPP on GPAI), 690 (Greens - on 3rd party conformity assessment), 693 ~~and 695 (TheLeft - reasonably foreseeable use)~~

(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.

(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

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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.

(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.

(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. ***The same should apply to updates of the AI system for security reasons in general and to protect against evolving threats of manipulation of the system, as lond as they do not amount to a substantial modification (AM 2196).***

Obtenu par CONTEXTE

COMP AM 5e
Covering: AMs ~~162 (Rapp),~~ 163 (Rapp), 2210 (Greens), 2212 (EPP), ITRE 66
Fall: AMs 2209 (ID), 2211 (ID), 2213 (Greens), 162 (Rapp)

Article 44
Certificates

1. Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in ***~~an~~ one or several*** official Union language***s*** determined by the Member State in which the notified body is established or in ***~~an~~ one or several*** official Union language***s (ITRE 66)*** otherwise acceptable to the notified body.

2. Certificates shall be valid for the period they indicate, which shall not exceed ***~~five~~ four*** years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding ***~~five~~ four*** years, based on a re-assessment in accordance with the applicable conformity assessment procedures. ***~~Any supplementary certificate shall remain valid for the same duration as the certificate which it supplements (AM 162)~~***

3. Where a notified body finds that an AI system no longer meets the requirements set out in Chapter 2 of this Title, it shall, ***~~taking account of the principle of proportionality~~ (AM 2210)***, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision.

Article 45
Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies, ***including on issued conformity certificates (AM 163)*** is available to parties having a legitimate interest in that decision.

Article 46
Information obligations of notified bodies

1. Notified bodies shall inform the notifying authority of the following:

   (a) any Union technical documentation assessment certificates, any supplements to those certificates, quality management system approvals issued in accordance with the requirements of Annex VII;

   (b) any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;

   (c) any circumstances affecting the scope of or conditions for notification;

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(d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Each notified body shall inform the other notified bodies of:

(a) quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;

(b) EU technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.

3. Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities ~~***covering the same artificial intelligence technologies***~~ ***(AM 2212)*** with relevant information on issues relating to negative and, on request, positive conformity assessment results.

COMP AM 5ee on matching recital:
Covering /
Falls: AM 697 (EPP)

(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. ***For physical high-risk AI systems, a physical CE marking should be affixed, and may be complemented by a digital CE marking. For digital only high-risk AI systems, a digital CE marking should be used.*** 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.

Obtenu par CONTEXTE

COMP AM 5f

Covering: AMs 164 (Rapp), 2214 (TheLeft), 2215 (S&D)
Fall: AMs 2216 (Greens), 2217 (EPP), 2218 (Greens), 2219 (Greens), 2220 (EPP), 2221 (Greens), 2222 (Greens)

Article 47
Derogation from conformity assessment procedure

1. By way of derogation from Article 43, any ~~***market surveillance***~~ ***national supervisory authority may request a judicial authority to (AM 2216)*** ~~***authority may***~~ authorise the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of ~~***public security or***~~ the protection of life and health of persons, environmental protection and the protection of ~~***key industrial and infrastructural assets***~~ ***critical infrastructure***. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.

2. The authorisation referred to in paragraph 1 shall be issued only if the ~~***market surveillance authority***~~ ***national supervisory authority and judicial authority*** conclude~~s~~ ***(AM 2218)*** that the high-risk AI system complies with the requirements of Chapter 2 of this Title. The ~~***market surveillance authority***~~ ***national supervisory authority*** shall inform the Commission, ***the AI office,*** and the other Member States of any ***request made and any subsequent (AM 2218)*** authorisation issued pursuant to paragraph 1.

3. Where, within 15 calendar days of receipt of the information referred to in paragraph 2, no objection has been raised by either a Member State or the Commission in respect ***to the request of the national supervisory authority for*** ~~of~~ ***(AM 2219)*** an authorisation issued by a ~~market surveillance authority~~ ***national supervisory authority*** of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.

4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2, objections are raised by a Member State against ~~an authorisation~~ ***a request (AM 2221)*** issued by a ~~market surveillance authority~~ ***national supervisory authority*** of another Member State, or where the Commission considers the authorisation ~~***request (AM 2221)***~~ to be contrary to Union law or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 2 to be unfounded, the Commission shall without delay enter into consultation with the relevant Member State ***and the AI Office***; the operator(s) concerned shall be consulted and have the possibility to present their views. In view thereof, the Commission shall decide whether the authorisation ~~***request (AM 2221)***~~ is justified or not. The Commission shall address its decision to the Member State concerned and the relevant operator***(s)*** ~~or operators~~. ***(AM 2221)***

Obtenu par CONTEXTE

5. If the authorisation ~~***request (AM 2222)***~~ is considered unjustified, this shall be withdrawn by the ~~market surveillance authority~~ ***national supervisory authority*** of the Member State concerned.

6. By way of derogation from paragraphs 1 to 5, for high-risk AI systems intended to be used as safety components of devices, or which are themselves devices, covered by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 shall apply also with regard to the derogation from the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title.

COMP AM 5ff on matching recital:
Covering: ~~AMs 34 (Rapp), 698 (Renew), 699 (Greens), 701 (S&D)~~
Falls: AM 700 (ID), AMs 34 (Rapp), 698 (Renew), 699 (Greens), 701 (S&D)

(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, ***environmental protection*** and the protection of ***critical infrastructure*** ~~***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.

Obtenu par CONTEXTE

COMP AM 5g
Covering: AMs 165 (Rapp), ~~166 (Rapp)~~, 167 (Rapp), 168 (Rapp), 169 (Rapp), ~~170 (Rapp),~~ 171 (Rapp), 172 (Rapp), 2223 part 2 (Greens), 2224 (S&D), 2225 (EPP), ~~2226 (S&D),~~ 2228 (EPP), 2230 (S&D), 2232 (Renew), 2233 (EPP), 2234 (Renew), 2235 (EPP), 2236 (S&D), 2238 (S&D), 2239 (EPP), 2240 (Greens), 2241 (Renew), 2242 (S&D), ~~2244 (Renew),~~ 2245 (EPP), ~~2247 (Greens),~~ 2248 (S&D), 2252 (Renew), 2253 (Greens), 2254 (ECR), 2256 (TheLeft), 2257 (Greens)
Fall: AMs 2223 part 1 (Greens), 2227 (Greens), 2229 (EPP), 2231 (ID), 2237 (EPP), 2243 (EPP), 2246 (TheLeft), ~~2247 (Greens),~~ 2249 (EPP), 2250 (EPP), 2251 (TheLeft), 2255 (S&D), 166 (Rapp), 2226 (S&D), 170 (Rapp)
Parked for later: 2244 (Renew),

Article 48
EU declaration of conformity

1. The provider shall draw up a written ***machine readable, physical or electronic (AM 2223, 2225)*** EU declaration of conformity for each ***high-risk (AM 165, 2224)*** AI system and keep it at the disposal of the national ***supervisory authority and the national (AM 2224)*** competent authorities for 10 years after the AI ***high-risk (AM 165, 2224)*** system has been placed on the market or put into service ~~***or for its entire lifecycle (AM 2224)***~~. ~~***The EU declaration of conformity shall identify the AI system for which it has been drawn up(AM 165).***~~ A copy of the EU declaration of conformity shall be ~~***given***~~ ***submitted (AM 2225)*** to the ***national supervisory authority and the (AM 2224)*** relevant national competent authorities upon request.

2. The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title ~~***including the requirements related to the respect of the Union data protection acquis (AM 166, 2226).***~~ The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is ***placed on the market or (AM 166, 2226)*** made available.

3. Where high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity ~~***shall***~~ ~~***can***~~ ***may (AM 167)*** be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates.

4. By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Chapter 2 of this Title. The provider shall keep the EU declaration of conformity up-to-date as appropriate.

5. ***After consulting the AI office*** ~~***Board***~~ ***(AM 2228),*** the Commission shall be empowered to adopt delegated acts in accordance with Article 73 for the purpose of updating the content of the EU declaration of conformity set out in Annex V in order to introduce elements that become necessary in light of technical progress.

Obtenu par CONTEXTE

Article 49
CE marking of conformity

1. The ***physical (AM 2232, 2233)*** CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems ***before the high-risk AI system is placed on the market (AM 168, 2230)***. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate. ***It may be followed by a pictogram or any other marking indicating a special risk of use (AM 2230).***

   1bis. For digital only high-risk AI systems, a digital CE marking shall be used, only if it can be easily accessed via the interface from which the artificial intelligence system is accessed or via an easily accessible ~~display of the product or via a~~ machine-readable code or other electronic means (AM 2234, 2235).1ter.

   ~~A digital CE marking may also be used instead of or additionally to the physical marking only if it can be easily accessed via the interface from which the artificial intelligence system is accessed or via an easily accessible display of the product or via a machine-readable code or other electronic means (AM 2234, 2235).~~

2. The CE marking referred to in paragraph 1 of this Article shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number ***of the notified body shall be affixed by the body itself or, under its instructions, by the provider's authorised representative. The identification number (AM 169)*** shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.

   3bis. Where high-risk AI systems are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other legislation (AM 2236).

   ~~3ter. The CE marking shall be affixed only after assessment of the compliance with Union data protection law (AM 170)~~

Article 50
Document retention

The provider shall, ***~~for the entire lifecycle of the AI system or~~*** for a period ending 10 years, after the AI system has been placed on the market or put into service ***(AM 2238, 2239, 2240, 2241, 2242)*** keep at the disposal of the national ***supervisory authority and the national (AM 2242)*** competent authorities:

(a) the technical documentation referred to in Article 11;

(b) the documentation concerning the quality management system referred to Article 17;

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(c) the documentation concerning the changes approved by notified bodies where applicable;

(d) the decisions and other documents issued by the notified bodies where applicable;

(e) the EU declaration of conformity referred to in Article 48.

Article 51
Registration

1. Before placing on the market or putting into service a high-risk AI system referred to in Article 6***(2)*** ***(~~AM 2247~~),*** the provider or, where applicable, the authorised representative shall register that system in the EU database referred to in Article 60***, in accordance with Article 60(2) (AM 171, 2248)***.

1. bis Before putting into service or using a high-risk AI system in accordance with Article 6(2), the following categories of ~~users~~ deployers shall register the use of that AI system in the EU database referred to in Article 60 (AM 172, 2252, 2254, 2257):

a) ~~users~~ deployers who are public authorities or Union institutions, bodies, offices or agencies or ~~users~~ deployers acting on their behalf

b) ~~users~~ deployers who are undertakings designated as a gatekeeper under Regulation 2022/1925;

1b. ~~users~~ Deployers who do not fall under subparagraph 1a. shall be entitled to voluntarily register the use of a high-risk AI system referred to in Article 6(2) in the EU database referred to in Article 60;

1c. An updated registration entry must be completed immediately following each substantial modification (AM 2253, 2254, 2256).

COMP AM 5gg covering matching recital
Covering: AMs 35 (Rapp), 702 (TheLeft), 703 (TheLeft), 704 (S&D)
Falls: AM 705 (Greens), AM 706 (EPP)

(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. ***This database should be freely and publicly accessible, easily understandable and machine-readable. The database should also be user-friendly and easily navigable, with search functionalities at minimum allowing the general public to search the database for specific high-risk systems, locations, categories of risk under Annex IV and keywords. ~~Users~~ Deployers who are public authorities or European Union institutions, bodies, offices and agencies or ~~users~~ deployers acting on their behalf and deployers who are undertakings designated as a gatekeeper***

Obtenu par CONTEXTE

under Regulation 2022/1925 ***should also register in the EU database before putting into service or using a high-risk AI system for the first time (AM 35, 704). Other deployers should be entitled to do so voluntarily. Any substantial modification*** ~~***uses***~~ ***of high-risk AI systems*** ~~***by public authorities or on their behalf***~~ ***shall also be registered in the EU database (AM 702).*** The Commission should be the controller of that database, in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[21]. 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 (AM 702, 703)***

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21 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).

COMP AM 5h
Covers: AMs 308, 309 (Rapp), 3294 (RE), 3295 (TheLeft), AMs 3296 (Greens), 3297 (Greens), 3299 (Greens), 3301 (Greens), 3302 (Greens), 3305 (EPP), 3306 (Greens)
Falls: AM 3288 (TheLeft), 3289 (S&D), 3290 (TheLeft), 3291 (Greens), 3292 (S&D), 3293 (Left), 3298 (S&D), 3303 (Greens), 3307 (TheLeft), 3308 (TheLeft), 3309 (TheLeft), 3310 (S&D)
Parked for later: ~~AMs 3296 (Greens), 3297 (Greens), 3298 (S&D),~~ 3304 (RE)

ANNEX VIII
INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51

Section A - The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article ***51 (1).***

1. Name, address and contact details of the provider;
2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;
3. Name, address and contact details of the authorised representative, where applicable;
4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;
5. ***A simple and comprehensible*** description of
    a. the intended purpose ~~***or reasonably foreseeable uses (AM 308, 3300)***~~ of the AI system;
    b. ***the components and functions supported through AI***
    c. ***a basic explanation of the logic of the AI system***
    d. ~~***the main parameters the AI system takes into account***~~
    e. ~~***arrangements for human oversight (AM 3299)***~~

~~***5a. where applicable, the categories of natural persons and groups likely or foreseen to be affected (AM 3301)***~~

5b. where applicable, the categories and nature of data likely or foreseen to be processed by the AI system (AM 3302)

6. Status of the AI system (on the market, or in service; no longer placed on the market/ in service, recalled);
7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;
8. A scanned copy of the certificate referred to in point 7, when applicable;
9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;
10. A copy of the EU declaration of conformity referred to in Article 48;
11. ~~***Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7. (AM 3305, 3306)***~~

Obtenu par CONTEXTE

12. URL for additional information (optional).

SECTION B - ***The following information shall be provided and thereafter kept up to date*** ~~***updated***~~ ***with regard to high-risk AI systems to be registered in accordance with Article 51***~~***(2)***~~ ***(1a(a) and (1b)*** ~~***by users who are or act on behalf of public authorities or Union institutions, agencies, offices or bodies:***~~

1. ***the name, address and contact details of the*** ~~***user***~~ ***deployer***
2. ***the name, address and contact details of the person submitting information on behalf of the*** ~~***user***~~ ***deployer***
3. ***the high-risk AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system used***
4. ***a. A simple and comprehensible description of the intended use of the AI system, including the specific outcomes sought through the use of the systemn, the geographic and temporal scope of application***
   b. Where applicable, the categories and nature of data to be processed by the AI system;
   c. Arrangements for human oversight and governance
   d. Where relevant, the bodies or natural persons responsible for decisions taken or supported by the AI system.

5. ***a summary of the findings of the fundamental rights impact assessment conducted in accordance with the obligation of public authorities or Union institutions, agencies, offices or bodies set out in this Regulation***
6. ***URL of the entry of the AI system in the EU database by its provider (AM 3295)***
7. ***a summary of the data protection impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 as specified in paragraph 6 of Article 29 of this Regulation, where applicable (AM 309, 3295)***

Obtenu par CONTEXTE

AI ACT - COMPROMISE AMENDEMENTS - BATCH 4 - V6-01.02.2023

TITLE 5: Measures in support of innovation

COMP AM 7a

Covering: AM 173 (Rapp), 174 (Rapp), 175 (Rapp), 176 (Rapp), 177 (Rapp), 178 (Rapp), AM 2288 (EPP), AM AM 2289 (Greens), AM 2290 (TheLeft), AM 2293 (Renew), AM 2294 (Renew), AM 2296 (S&D), 2298 (Renew), 2300 (Renew), 2301 (S&D), 2305 (EPP), 2306 (EPP), 2308 (Greens), 2311 (Renew), 2312 (EPP), 2313 (Greens), 2314 (The Left), 2315 (EPP), 2316 (S&D), 2317 (S&D), 2318 (Renew), 2319 (EPP), 2321 (EPP), 2322 (EPP), 2323 (EPP), 2324 (Renew), 2325 (EPP), 2326 (EPP), 2327 (Greens), 2328 (S&D), 2329 (Renew), 2330 (Renew), 2331 (TheLeft), 2333 (Renew), 2334 (Renew), 2335 (Greens), 2336 (EPP),

2337 (EPP), 2338 (TheLeft), 2340 (Renew), 2341 (Renew), 2342 (EPP), ITRE 70, ITRE 72, ITRE 73, ITRE 74, ENVI 87, TRAN 101, TRAN 103, TRAN 104, 3311 (EPP), 3312 (RE), 83 (ITRE), ***2880 (EPP), 2881 (RE),1099 (EPP), 1103 (RE), ITRE 27***
Fall: AMs 2291 (EPP), AM 2292 (EPP), 2295 (Renew), 2297 (ECR), 2302 (EPP), 2304 (EPP), 2306 (EPP), 2307 (S&D), 2309 (Renew), 2310 (TheLeft), 2320 (EPP), 2332 (ECR), ENVI 88, TRAN 100, TRAN 102, ITRE 71
Parked for later: AM 2299, 2339

Article 3
New definition

(44h) 'regulatory sandbox' means a framework that provides a controlled environment established by a public authority that facilitates the safe development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan under regulatory supervision; (AM 1099 (EPP), 1103 (RE))

Article 52
Transparency obligations

1. ***Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that the AI system, the provider itself or the user informs the natural person exposed to an AI system that they are interacting with an AI system in a timely, clear and intelligible manner, unless this is obvious from the circumstances and the context of use. Where appropriate and relevant, this information shall also include which functions are AI enabled, if there is human oversight, and who is responsible for the decision-making process, as well as the existing rights and processes that, according to Union and national law, allow natural persons or their representatives to object against the application of such systems to them and to seek judicial redress against decisions taken by or harm caused by AI systems, including their right to seek an explanation. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.***

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

3. Users of an AI system that generates or manipulates text, audio or visual content that would falsely appear to be authentic or truthful and which features depictions of people appearing to say or do things they did not say or do, without their consent ('deep fake'),

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

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

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

TITLE V

MEASURES IN SUPPORT OF INNOVATION

Article 53
AI regulatory sandboxes

1. ***Member States shall establish (AM 2288, 2293) at least one*** AI regulatory sandbox ***at national level ~~with national coverage~~, which shall be operational at the latest on the day of the entry into application of this Regulation (AM 2288, 2293), ~~established by one or more Member States competent authorities or the European Data Protection Supervisor~~ (AM 2288). This ~~mandatory~~ sandbox can also be established jointly with one or several other Member States ~~as long as the sandbox covers their respective national level.~~***

1a. ~~Member States may also establish~~ Additional AI regulatory sandboxes at ~~national,~~ regional or local levels (AM 2293) or jointly with other Member States (AM 2301~~) in order to facilitate cross-border and cross-sectorial cooperation and synergies (AM 2322)~~ may also be established.

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~~*1aa. For the purpose of paragraph 1 and 1a, the Commission shall play a complementary role, allowing enabling those Member States with demonstrated experience with sandboxing to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes (AM 2288).*~~

1b. The Commission and the European Data Protection Supervisor, on their own, jointly or in collaboration with one or more Member States ~~*competent authorities*~~ ***(AM 2290, 2294)*** ~~*and or*~~ ~~the European Data Protection Supervisor~~ ***may also establish AI regulatory sandboxes at Union level.***

1bb. ~~*Member States*~~ ***Establishing authorities*** shall ***allocate*** ~~*ensure that*~~ ~~the national competent authorities~~ ~~*responsible for the regulatory sandboxes have*~~ ***sufficient resources*** ~~*available*~~ ***to comply with this Article*** ~~*fulfil their duties in this regard*~~ ***effectively and in a timely manner (AM 2293).***

~~*1bbb. Establishing authorities shall inform the AI office of the establishment of a sandbox and may ask for support and guidance. Exit reports with lessons learned from participation in sandboxes shall be transmitted to the AI Office on a trimestral basis. A list of planned and current sandboxes shall be made publicly available by the AI office (AM 2335) and kept up to date in order to encourage more interaction in the regulatory sandbox ecosystem and transnational cooperation.*~~

1c. AI regulatory sandboxes shall, ***in accordance with*** ~~*based on well-established*~~ ***criteria (AM 2288) set out in Article 53a,*** provide ***for*** a controlled environment ***that fosters innovation and*** ~~*that facilitates*~~ ***facilitates*** ~~*ing*~~ ***(AM 2296)*** the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service ***pursuant to a specific plan agreed between the prospective providers*** ~~*participants*~~ ***and the establishing authority (AM 2296, 2298).***

1c. The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:

a) for the competent authorities to provide guidance to AI systems ~~*developers providers and*~~ ***prospective providers to achieve regulatory compliance with this Regulation or where relevant other applicable Union and Member States legislation***

b) for the prospective providers ~~*developers*~~ ***to allow and facilitate the testing and development of innovative solutions related to AI systems***

c) regulatory learning ~~*testing of potential adaptations of this Regulation*~~ ***in a controlled environment***

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a) ~~foster innovation and competitiveness and facilitate the development of an AI ecosystem;~~

b) ~~facilitate and accelerate access to the Union market for AI systems, including by small and medium entreprises (SMEs) and start-ups;~~

c) ~~improve legal certainty through cooperation with the authorities involved in the AI regulatory sandbox with a view to ensuring compliance with this Regulation and where appropriate, with other Union and Member States legislation;~~

d) ~~contribute to the uniform and effective implementation of this Regulation~~

e) ~~contribute to the development or update of harmonised standards and common specifications referred to in Articles 40 and 41 and their uptake by providers (AM 2303)~~

1d. Establishing authorities shall provide guidance and supervision ~~on the creation of sandboxes and~~ within the sandbox ~~establishment and functioning of sandboxes This~~ shall ~~take place under the direct supervision and guidance by the~~ ***~~national~~*** ~~competent authorities~~ ***~~or by the Commission or the EDPS when they have established the sandbox,~~*** with a view to ***identify risks, in particular to fundamental rights, democracy and rule of law, health and safety and the environment (AM 2288, 2289, 2290, 2294, ENVI 87, TRAN 103), test and demonstrate mitigation measures for identified risks, ~~demonstrate prevention~~ and their effectiveness ~~of these risks~~ and (AM 2288)*** ensur***~~ing~~*** compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation ***~~supervised within the sandbox~~ (AM 173). ~~Regulatory sandboxes shall operate in full compliance with Regulation 2016/679 (AM 2290).~~***

1e. Establishing authorities shall provide sandbox prospective providers ~~participants~~ who develop high-risk AI systems with guidance and supervision on how to fulfil the requirements set out in this Regulation, so that the AI systems may exit the sandbox being in presumption of conformity with the specific requirements of this Regulation that were assessed within the sandbox. Insofar as the AI system complies with the requirements when exiting the sandbox, it shall be presumed to be in conformity with this regulation. In this regard, the exit reports created by the establishing authority shall be taken into account by market surveillance authorities or notified bodies, as applicable, in the context of conformity assessment procedures or market surveillance checks.

2. ***Establishing authorities*** ~~Member States, ***the Commission and the EDPS***~~ shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to ***personal (AM 175, 2306, 2311)*** data, the national data protection authorities, ***or in cases referred to in paragraph 1b ~~where applicable~~ the EDPS***, and those other national authorities are associated to the operation of the AI regulatory sandbox ***and involved in the***

Obtenu par COMTEXTE

~~control~~ supervision of those aspects ~~of the sandbox they supervise~~ to the full extent of their respective tasks and powers (AM 2308).

3. The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities, ***including at regional or local level (ITRE 72)***. Any significant risks to fundamental rights, ***democracy and rule of law, health and safety or the environment (AM 2313, 2314, 2316, 2317)*** identified during the development and testing of such ***AI (AM 2319)*** systems shall result in immediate ***and adequate (AM 176)*** mitigation ***~~and, failing that, in the suspension of~~***. ***~~Where such mitigation proves to be ineffective or where mitigation measure cannot be identified to stop and remedy such significant risk or harm (AM 2313),~~*** ~~the development and testing process~~ ***~~shall be suspended by the competent authorities without delay until effective such mitigation takes place~~ (AM 176, 2316, 2317, 2318)***. ***Competent authorities shall have the power to temporarily or permanently suspend the ~~development and~~ testing process, or participation in the sandbox if no effective mitigation is possible (AM 2313) and inform the ~~European Artificial intelligence board~~ AI office of such decision ~~without delay~~.***

4. ***Prospective providers ~~Participants~~*** in the AI regulatory sandbox shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result ***~~from~~ of (AM 177, 2321)*** the experimentation taking place in the sandbox. ***However, provided that the prospective provider(s) ~~participant(s)~~ respect the ~~sandbox~~ specific plan referred to in paragraph 1c and the terms and conditions for their participation and follow in good faith the guidance given by the establishing authorities, no administrative fines ~~enforcement action~~*** shall ***be imposed by the authorities for infringements of this Regulation. ~~applicable Union or Member State legislation~~ (AM 2315, 2880, 2881)***

5. ***Establishing authorities ~~Member States'~~*** ~~competent authorities~~, ***~~the Commission (AM 2331) and the EDPS~~ ~~that have established AI regulatory sandboxes~~ (AM 178, 2330)*** shall coordinate their activities and cooperate within the framework of the ***AI office ~~European Artificial Intelligence Board, the Commission's AI Regulatory sandboxing programme referred to in paragraph 6b (AM 2329) and, to the extent possible, with the European digital innovation hubs (AM 2323).~~***

~~5b. Regulatory sandboxes shall allow and facilitate the testing of possible adaptations of the regulatory framework governing artificial intelligence in order to enhance innovation or reduce compliance costs, without prejudice to the provisions of this Regulation or to while guaranteing the protection of the health, safety, fundamental rights of natural persons, the environment or to the values of the Union as enshrined in Article 2 TEU. The results from such tests shall be submitted to the AI Office Board and the Commission (AM 2323, 2333).~~

5a. Establishing authorities shall inform the AI Office of the establishment of a sandbox and may ask for support and guidance. ~~Exit reports with lessons learned, results from participation in sandboxes shall be regularly transmitted to the AI Office on trimestrial basis.~~ A list of planned and existing ~~current~~ sandboxes shall be made publicly available by

Obtenu par COVERTME

the AI office (AM 2335) and kept up to date in order to encourage more interaction in the regulatory sandboxes ~~ecosystem~~ and transnational cooperation.

5b. ***Establishing authorities ~~Member States' competent authorities, the Commission and the EDPS~~*** shall submit ***~~during the whole duration of the sandbox, annual reports~~*** to the ***AI office ~~Board~~*** and, ***unless the Commission is the sole establishing authority, ~~where relevant~~ to*** the Commission, ***~~where relevant~~ annual reports, starting one year after the establishment of the sandbox and then every year until its termination and a final report. Those reports shall provide information*** on the ***progress and*** results ***~~from~~ of*** the implementation of those ***sandboxes ~~schemes~~ (AM 2323, 2325, 2326, 2328)***, including ***best ~~good~~ (ITRE 73)*** practices, ***incidents (178, 2324, 2328), ~~computational energy use and efficiency (ITRE 73),~~*** lessons learnt and recommendations on their setup and, where relevant, on the application ***and possible revision (AM 2327)*** of this Regulation and other Union legislation supervised within the sandbox ***~~as referred to in paragraph 5a, notably with regards to easing burdens and introducing further regulation where additional risks and potential harms are identified~~ (AM 2326, 2327). Those annual reports or abstracts thereof shall be made available to the public, online. ~~in order to further enable innovation in the Union~~ (AM 178, 2323). ~~The annual reports shall also be submitted to the AI Board which shall publish on its website a summary of all good practices, lessons learned, potential risks, harms and recommendations (AM 2324, 2325, 2326, 2327, 2328, 2330).***

~~5b. Regulatory sandboxes shall allow and facilitate the testing of possible adaptations of the regulatory framework governing artificial intelligence in order to enhance innovation or reduce compliance costs, without prejudice to the provisions of this Regulation or to while guaranteeing the protection of the health, safety, fundamental rights of natural persons, the environment or to the values of the Union as enshrined in Article 2 TEU. The results from such tests shall be submitted to the AI Board and the Commission (AM 2323, 2333).~~

6. The Commission shall develop a single and dedicated interface containing all relevant information related to sandboxes, together with a single contact point at EU level to interact with the regulatory sandboxes ~~ecosystem~~ and to allow stakeholders to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity of innovative products, services, business models embedding AI technologies (ITRE AM 83)

The Commission shall proactively coordinate with national, regional and also local authorities, where relevant.

7. For the purpose of paragraph 1 and 1a, the Commission shall play a complementary role, ~~allowing~~ enabling ~~those~~ Member States ~~with demonstrated experience with sandboxing~~ to build on their expertise and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up and running of these regulatory sandboxes (AM 2288).

OUTNUMBER CONFIDENTIAL

Obtenu par CONTEXTE

Modalities and functioning of AI regulatory sandboxes

~~6.~~ *1. In order to avoid ~~to avoid~~ fragmentation across the Union, the Commission, in consultation with the AI office, shall adopt a delegated ~~implementing~~ act detailing the modalities for the establishment, development, implementation, ~~and the conditions of the operation of the~~ functioning and supervision of* the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants ~~*shall be,*~~ *based on the ~~guidance~~ provisions ~~criteria~~ set out in this Article ~~set out in implementing acts, in close cooperation with relevant stakeholders (AM 2337)~~.*

2. The Commission is empowered to adopt ~~This~~ delegated acts ~~shall be adopted~~ in accordance with the ~~the examination~~ procedure referred to in Article 73 ~~74(2),~~ no later than 12 months following the entry into force of this Regulation and shall ensure that ~~the following~~: ~~(AM 2334, 2338):~~

a) ~~that~~ regulatory sandboxes are open to any applying prospective provider of an AI system who fulfils ~~national~~ eligibility and selection criteria. The criteria for accessing to the regulatory sandbox shall be transparent and fair ~~competitive~~ (ITRE AM 83) ~~Supervising~~ Establishing authorities shall inform applicants of their decision within 3 months of the application (AM 2289, 2312).

b) ~~that they~~ regulatory sandboxes allow broad and equal access and keep up with demand for participation ~~without creating disincentivising backlogs or delays~~ (AM 2334)

c) ~~that~~ access to the AI regulatory sandboxes is free of charge for SMEs and start-ups without prejudice to exceptional costs that ~~national competent~~ establishing authorities may recover in a fair and proportionate manner (2312)

d) ~~that~~ regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem (AM 2305), such as notified bodies and standardisation organisations (AM 174, 2300) SMEs, start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and digital innovation hubs (AM 2305), centers of excellence, individual researchers, ~~innovators and entrepreneurs~~ (AM 2238), in order to allow and facilitate cooperation with the public and private sector (AM 2288, 2300, 2306, 2338, TRAN 101)

(e) ~~that~~ they allow prospective providers ~~SMEs and start-ups~~ ~~and SMEs~~ to ~~and in order for them~~ to fulfil, in a controlled environment, the conformity assessment obligations of this Regulation or the voluntary application of the codes of conduct referred to in Article 69 (AM 2334, 2338);

e) ~~that adequate resources are dedicated to the establishment and functioning of the regulatory sandboxes (AM 2334)~~

f) ~~that~~ procedures, processes and administrative requirements for application, selection, participation and exiting the sandbox are simple, easily intelligible, clearly communicated in order to facilitate the participation of SMEs and start-ups

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with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation ~~in the regulatory sandboxes across Member States as much as possible~~ (AM 2338) and that participation in a regulatory sandbox established by a Member State, by the Commission, or by the EDPS is mutually and uniformly recognised and carries the same legal effects across the Union (AM 2334);

~~g) that procedures, processes, and bureaucratic administrative requirements for application, selection, participation, and exiting the sandbox shall be are simple, easily, intelligible, clearly communicated, and streamlined so as to facilitate the participation of start-ups with limited legal and bureaucratic administrative capacities (AM 2334)~~

h) ~~that~~ participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project (AM 2312)

i) the sandboxes shall facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity as well as minimisation of risks to fundamental rights, environment and the society at large

3. Prospective providers ~~participants~~ in the sandboxes ~~sandboxing programme~~, in particular SMEs and start-ups, shall be ~~granted access to:~~ facilitated access to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and certification and consultation, and to other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities.

~~a) pre-deployment services such as guidance on the implementation of this Regulation, support services for R&D compliance, and all the other relevant elements of the Union's AI ecosystem, and to other value-adding services such as help with standardisation documents and certification and consultation and support for assessing the AI systems~~

~~b) be granted access to other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities~~

~~c) access to an online social platform for the community, contact databases, existing portals for tenders and grant making, and lists of EU investors (ITRE AM 83)~~

~~6a. The Commission shall draw up guidelines for the proper establishment, development, implementation, functioning, and supervision of regulatory sandboxes (AM 2341)~~

Obtenu par CONTEXTE

6b. ~~Establishing authorities The national competent authorities, the Commission and the EDPS shall inform the AI office European Artificial Intelligence Board of the establishment of regulatory sandboxes (AM 2289). A list of planned and current sandboxes shall be made publicly available by the European Artificial intelligence Board (AM 2335) and kept up to date in order to encourage more interaction in the regulatory sandbox ecosystem and transnational cooperation (AM 2238). The Commission shall develop a single and dedicated interface and contact point at the EU level to interact with the regulatory sandbox ecosystem and to allow stakeholders to raise enquiries with competent authorities, and to seek non-binding guidance (ITRE AM 83)~~

6b. The Commission shall establish an EU AI Regulatory Sandboxing Programme whose modalities referred to in Article 53(6) shall cover the elements set out in Annex IXa. The Commission shall proactively coordinate with national, regional and also local authorities, where relevant (AM 2340, 2341, 2342, ITRE 74)

Obtenu par CONTEXTE

~~*ANNEX IXa*~~

~~*Modalities for an EU AI regulatory sandboxing work programme*~~

~~*1. The AI Regulatory Sandboxes shall be part of the EU AI Regulatory Sandboxing Work Programme ('sandboxing programme') to be established by the Commission in collaboration with Member States.*~~

~~*2. The Commission shall play a complementary role, allowing those Member States with demonstrated experience with sandboxing to build on their expertise and the expertise of relevant stakeholders from industry, SMEs, academia and civil society and, on the other hand, assisting and providing technical understanding and resources to those Member States that seek guidance on the set-up of these regulatory sandboxes.*~~

~~*3. The criteria for the access to the regulatory sandbox shall be transparent and competitive.*~~

~~*4. Participants in the sandboxing programme, in particular small-scale providers, are granted access to pre-deployment services, such as preliminary registration of their AI system, compliance R&D support services, and to all the other relevant elements of the Union's AI ecosystem and other Digital Single Market initiatives such as Testing & Experimentation Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities; and to other value-adding services such as standardisation documents and certification, consultation and support to conduct impact assessments of the AI systems to safety, health, fundamental rights, environment or European values as enshrined in Article 2 TFEU the society at large, an online social platform for the community, contact databases, existing portal for tenders and grant making and lists of EU investors.*~~

~~*5. The sandboxing programme shall work with the already established Digital Innovation Hubs in Member States to provide a dedicated point of contact for entrepreneurs to raise enquiries with competent authorities and to seek non-binding guidance on the conformity of innovative products, services or business models embedding AI technologies.*~~

~~*6. One of the objectives of the sandboxing programme is to enable firms' compliance with this Regulation at the design stage of the AI system ('compliance-by-design'). To do so, the programme shall facilitate the development of software tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant to sandboxes, such as accuracy, robustness and cybersecurity as well as minimisation of risks to fundamental rights, environment and the society at large.*~~

~~*7. The sandboxing programme will have a built-in impact assessment procedure to facilitate the review of cost-effectiveness against the agreed-upon objectives. This assessment shall be drafted with input from Member States based on their experiences and shall be included as part of the Annual Report referred to Article 53(5). submitted by the Commission to the European Artificial Intelligence Board. (AMs ITRE 83, 2338, 3311, 3312)*~~

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8. The sandboxing programme and its benefits shall be available from a single portal established by the European Commission.

Obtenu par CONTEXTE

COMP AM 7b
Concerned AMs 2343 to 2369
Covering: 2347 (RE); 2348 (EPP); 2349 (Greens); 2351 (Greens); 2353 (Greens); 2355 (EPP), 2360 (EPP); 2361 (EPP); 2363 (EPP); 2365 (RE); 2366 (Greens); 2369 (S&D); 2388 (The Left); 2389 (RE); ENVI 89; ENVI 90; TRAN 105
Fall: 2343 (S&D); 2344 (RE); 2345 (S&D); 2346 (Greens) 2350 (EPP); 2352 (RE); 2354 (ID); 2356 (Greens); 2357 (Greens), 2358 (EPP); 2359 (Greens), 2362 (Greens), 2364 (Greens), 2367 (EPP), 2368 (Greens), ENVI 91

Article 54
Further processing of ~~personal~~ data for developing certain AI systems in the public interest in the AI regulatory sandbox

1. In the AI regulatory sandbox personal data ***~~and data protected by intellectual property rights or trade secrets (AM 2346)~~*** lawfully collected for other purposes ~~shall~~ ***may (AM 2348)*** be processed ***solely (AM 2346)*** for the purposes of developing and testing certain ~~innovative~~ ***(AM 2346)*** AI systems in the sandbox ~~under~~ ***when all of*** the following conditions ***are met***: ***(AM 2347)***

   (a) ~~the innovative~~ ***(AM 2349)*** AI systems shall be developed for safeguarding substantial public interest in one or more of the following areas:

      ~~(i) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;~~ ***(AMs 2351)***

      (ii) public safety and public health, including disease ***detection, diagnosis (AM ENVI 89)*** prevention, control and treatment;

      (iii) a high level of protection and improvement of the quality of the environment, ***protection of biodiversity, pollution as well as climate change mitigation and adaptation; (AMs, 2353; ENVI 90)***

      (iiia) safety and resilience of transport systems, critical infrastructure and networks.(AM TRAN 105)

   (b) the data processed are necessary for complying with one or more of the requirements referred to in Title III, Chapter 2 where those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data;

   (ba) ~~the principle of data minimisation shall be upheld, meaning that the data acquisition and processing shall be kept to what is strictly necessary for the purpose of the artificial intelligence application; (AM ENVI 91)~~

   (c) there are effective monitoring mechanisms to identify if any high risks to the ***~~fundamental~~*** rights ***and freedoms*** of the data subjects, ***as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 35 of Regulation (EU) 2018/1725 ~~and holders of intellectual property rights or trade secrets (AM~~***

Obtenu par CONTEXTE

~~*2356)*~~ may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing***; (AM 2355)***

(d) any personal data ~~***or data protected by intellectual property rights or trade secrets (AM 2357)***~~ to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the ***prospective providers*** ~~***participants***~~ and only authorised persons have access to ~~that~~ ***those (AM 2357)*** data;

(e) any personal data ~~***or data protected by intellectual property rights or trade secrets (AM 2359)***~~ processed are not be transmitted, transferred or otherwise accessed by other parties;

(f) any processing of personal data in the context of the sandbox do not lead to measures or decisions affecting the data subjects ***nor affect the application of their rights laid down in Union law on the protection of personal data***; ***(AM 2360)***

(g) any personal data ~~***or data protected by intellectual property rights or trade secrets (AM 2362)***~~ processed in the context of the sandbox are ***protected by means of appropriate technical and organisational measures and (AM 2361)*** deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

(h) the logs of the processing of personal data ~~***or data protected by intellectual property rights or trade secrets (AM 2364)***~~ in the context of the sandbox are kept for the duration of the participation in the sandbox ~~and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application Union or Member States legislation~~; ***(AM 2363)***

(i) complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation in Annex IV;

(j) a short summary of the AI ~~project~~ ***system (AM 2366)*** developed in the sandbox, its objectives***, hypotheses,*** and expected results***,*** ~~***and non-confidential results (AM 2365)***~~ published on the website of the competent authorities.

2. Paragraph 1 is without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation ~~***or to Union or Member States legislation excluding the use of data protected by intellectual property or trade secrets under the conditions covered by Paragraph 1. (AM 2368)***~~

Article 54 a

Promotion of AI research and development in support of socially and environmentally beneficial outcomes

Obtenu par CONTEXTE

1. Member States shall promote research and development of AI solutions which support socially and environmentally beneficial outcomes, including but not limited to development of AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, and meet sustainability and environmental targets, by:

(a) providing relevant projects with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions;

(b) earmarking public funding, including from relevant EU funds, for AI research and development in support of socially and environmentally beneficial outcomes;

(c) organising specific awareness raising activities about the application of this Regulation, the availability of and application procedures for dedicated funding, tailored to the needs of those projects;

(d) where appropriate, establishing accessible dedicated channels, including within the sandboxes, for communication with projects to provide guidance and respond to queries about the implementation of this Regulation.

2. Member States shall support ~~ensure that relevant projects are led by~~ civil society and social stakeholders to lead or participate in such ~~that set the~~ projects ~~priorities, goals, and outcomes.~~ (AM 2369, 2388, 2389).

Obtenu par CONTEXTE

COMP AM 7c on matching recitals

Covering: AMs 718 (TheLeft), 719 (Greens), 720 (RE), 721 (EPP), 723 (EPP), 724 (S&D), 725 (TheLeft) 728 (S&D), AMs 2303 (EPP), ENVI 47, TRAN 25, ITRE 12, ITRE 13, ITRE 14

Fall: 721 (EPP), 722 (S&D), 726 (S&D), 727 (S&D), ENVI 46, TRAN 26

(71) Artificial intelligence is a rapidly developing family of technologies that requires ~~***novel forms of***~~ ***(719)*** regulatory oversight and a safe ***and controlled (718)*** 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,***~~ ***promotes innovation (719), is*** future-proof, and resilient to disruption, ~~***national competent authorities from one or more***~~ Member States should ~~***be encouraged to***~~ establish ***at least one*** artificial intelligence regulatory sandbox 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. ***It is indeed desirable for the establishment of regulatory sandboxes, which establishment is currently left at the discretion of Member States, as a next step to be made mandatory with established criteria (ITRE 14). That mandatory sandbox could also be established jointly with one or several other Member States, as long as that sandbox would cover the respective national level of the involved Member States. Additional sandboxes may also be established at different levels, including cross Member States, in order to facilitate cross-border cooperation and synergies. With the exception of the mandatory sandbox at national level, Member States should also be able to establish virtual or hybrid sandboxes. All regulatory sandboxes should be able to accommodate both physical and virtual products. Establishing authorities should also ensure that the regulatory sandboxes have the adequate financial and human resources for their functioning (720).***

(72) The objectives of the regulatory sandboxes should be: ***for the establishing authorities to increase their understanding of technical developments, improve supervisory methods and provide guidance to AI systems developers and providers to achieve regulatory compliance with this Regulation or where relevant, other applicable Union and Member States legislation, as well as with the Charter of Fundamental Rights (725) ; for the prospective providers to allow and facilitate*** ~~***foster AI innovation by establishing a controlled experimentation and***~~ ***the*** testing ~~***environment in the***~~ ***and*** development ***of innovative solutions related to AI systems in the*** ~~***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 under to***~~ to enhance legal certainty ~~***for innovators, ;***~~ ***to allow for more regulatory learning by establishing authorities in a controlled environment to develop better guidance and to identify possible future improvements of the legal framework through the ordinary legislative procedure.*** ~~***and the competent establishing 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.***~~ ***Any significant risks identified during the development and testing of such AI systems should result in immediate***

Object pat COMPETE

mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. (718, ITRE 12). 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. ***Member States should ensure that regulatory sandboxes are widely available throughout the Union, (TRAN 25, ITRE 12). It is especially important to ensure that SMEs and startups can easily access these sandboxes, are actively involved and participate in the development and testing of innovative AI systems, in order to be able to contribute with their knowhow and experience. Their participation should remain voluntary and be supported and facilitated (TRAN 25)***

New 72a) 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 ***only under specified conditions (724)***, 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. ***prospective providers ~~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, ***health and the environment (ENVI 47)*** and fundamental rights that may arise during the development and experimentation in the sandbox. The conduct of the ***prospective providers ~~participants~~*** in the sandbox should be taken into account when competent authorities decide ***over the temporary or permanent suspension of their participation in the sandbox (724)*** whether to impose an administrative fine under Article 83(2) of Regulation 2016/679 and Article 57 of Directive 2016/680.

72 b) 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 (728)

Obtenu par CONTEXTE

AI ACT - COMPROMISE AMENDEMENTS - BATCH 8 – V4- 05.04.2023
TITLE VI: GOVERNANCE

COMP AM 8a
Covering: AMs 179 (Rapp.), 180 (Rapp.), 181 (Rapp.), 182 (Rapp.), 183 (Rapp.), 184 (Rapp.), 185 (Rapp.), 186 (Rapp.), 187 (Rapp.), 188 (Rapp), 189 (Rapp), 191 (Rapp), 192 (Rapp), 193 (Rapp), 194 (Rapp), 195 (Rapp), 196 (Rapp), 197 (Rapp), 198 (Rapp), 200 (Rapp), 201 (Rapp), 202 (Rapp), 203 (Rapp), 204 (Rapp), 205 (Rapp), 206 (Rapp), 207 (Rapp), 208 (Rapp), 209 (Rapp), 210 (Rapp), 211 (Rapp), 2392 (RE), 2394 (RE), 2397 (RE), 2398 (EPP), 2399 (S&D), 2400 (RE), 2401 (S&D), 2402 (Left), 2403 (Left), 2404 (RE), 2405 (RE), 2407 (EPP); 2408 (RE), 2409 (EPP), 2410 (RE), 2411 (Left), 2413 (S&D), 2414 (RE), 2415 (Greens), 2416 (EPP),), 2419 (TheLeft), 2420 (Left), 2421 (RE), 2422 (RE), 2423 (RE), 2424 (RE), 2425 (RE),), 2426 (RE), 2427 (RE), 2428 (S&D), 2429 (EPP), 2430 (Greens), 2431 (RE), 2432 (Left), 2435 (Left), 2436 (EPP), 2437 (S&D), 2439 (RE), 2440 (S&D), 2441 (S&D), 2442 (S&D), 2443 (S&D), 2444 (Left), 2445 (Greens),), 2447 (EPP), 2448 (Left), 2449 (S&D), 2450 (S&D), 2451 (Left), 2454 (S&D), 2455 (EPP), 2456 (Greens), 2457 (EPP), 2458 (S&D), 2459 (Left), 2461 (Left), 2462 (EPP), 2463 (Greens), 2464 (RE), 2465 (Left), 2466 (S&D), 2468 (RE), 2469 (S&D), 2471 (RE), 2472 (RE), 2473 (RE), 2474 (RE), 2475 (RE), 2477 (RE), 2479 (Greens), 2481 (Greens), 2482 (Greens), 2483 (Greens), 2486 (RE), 2488 (Left), 2489 (S&D), 2491 (EPP), 2492 (S&D), 2493 (RE), 2494 (RE), 2495 (RE), 2496 (RE), 2497 (RE), 2498 (RE), 2499 (EPP), 2501 (RE), 2502 (RE), 2503 (S&D), 2504 (S&D), 2505 (RE), 2506 (RE), 2507 (RE), 2508 (EPP), 2509 (EPP), 2510 (EPP), 2511 (EPP), 2512 (EPP), 2513 (RE), 2514 (S&D), 2515 (S&D), 2516 (RE), 2518 (S&D), 2519 (RE), 2520 (Left), 2521 (RE), 2522 (EPP), 2523 (RE), 2524 (Left), 2525 (EPP), 2526 (RE), 2527 (S&D), 2528 (RE), 2529 (RE), 2530 (S&D), 2531 (EPP), 2532 (S&D), 2533 (RE), 2534 (RE), 2535 (EPP), 2536 (EPP), 2537 (S&D), 2538 (RE), 2539 (RE), 2540 (RE), 2541 (EPP), 2542 (S&D), 2543 (RE), 2544 (RE), 2545 (RE), 2546 (RE), 2548 (RE), 2549 (RE), 2550 (S&D), 2551 (S&D), 2552 (RE), 2554 (Greens), 2555 (RE), 2603 (S&D)
Fall: AMs 199 (Rapp), 2393 (ECR), 2395 (S&D), 2396 (Left), 2417 (Left), 2418 (Left), 2426 (ECR), 2433 (ID), 2434 (ECR), 2438 (Left), 2444 (Left), 2446 (ID), 2452 (ID), 2453 (ECR), 2460 (S&D), , 2467 (EPP), 2470 (Greens), 2476 (ECR), 2478 (Greens), 2480 (Greens), 2484 (RE), 2485 (S&D), 2487 (Greens), 2500 (S&D), 2509 (EPP)
Parked: 2412 (EPP) and 2517 (Left) on GPAI; 2553 (EPP) on guidelines;

Chapter 1: European Artificial Intelligence ~~*Board*~~ *Office (AM 2392)*

SECTION 1: General provisions on the European Artificial Intelligence Office

Article 56
Establishment of the European Artificial Intelligence ~~Board~~ ***Office (AM 2394)***

1. ***The 'European Artificial Intelligence Office' (the 'AI Office') is hereby established. The AI Office shall be an independent body of the Union. (AMs 179, 2428) It shall have legal personality.***

Obtained from CONSILIUM

2. *The ~~European Union Artificial Intelligence~~ AI Office ~~shall have legal personality, and~~ shall have a secretariat, and shall be adequately funded and staffed for the purpose of ~~to~~ performing its tasks pursuant to this Regulation. (AMs 195, 2398, 2399, 2400, 2402, 2419, 2458).*

3. *The seat of the AI Office shall be in Brussels.*

Article 56a

~~Administrative and management~~ Structure

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

(a) a management board, including ~~with~~ a chair

(b) a secretariat managed by an executive director;

;

(c) an advisory forum.

~~(d) where appropriate, other advisory bodies established by the management board to support the AI Office in technical or scientific matters related to this Regulation. (AM 2424)~~

Article 56b

~~Mandate~~Tasks of the AI Office

The AI Office shall carry out the following tasks:

a. *~~carry out the tasks assigned to it under this Regulation;~~*

b. *to support, advise, and cooperate with Member States, national supervisory authorities, the Commission and other Union institutions, bodies, offices and agencies ~~in matters pertaining~~ with regard to the implementation of this Regulation;*

c. *to monitor and ensure the effective and consistent application of this Regulation, ~~subject to the remit of national supervisory authorities~~ without prejudice to the tasks of national supervisory authorities (AM 2403);*

d. *to ~~ensure~~ contribute to the coordination among national supervisory authorities responsible for the application of this Regulation~~, including~~*

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~~*by decisions with regard to serious disagreements between two or more Member States as set out in Article 59a;*~~

e. ~~*adopt decisions for national supervisorycompetent authorities in cases of serious disagreements as regards the leading authority for supervision assist national competent authorities with regard to the decision on the leading authority for supervision as set out in Article 59a'; (AMs 209, 2536, 2546, 2550);*~~ *serve as a mediator in discussions about serious disagreements that may arise between competent authorities regarding the application of the Regulation*

f. to coordinate joint investigations, ~~*as set out in*~~ *pursuant to Article 66a;*

g.~~*support the development of regulatory sandboxes provided for in this Regulation;*~~

ga.contribute to the effective cooperation with the competent authorities of third countries and with international organisations.

~~*Article 58* **56c**~~
~~*Tasks of the Board* **(AM 2476, 2477)**~~

~~When providing advice and assistance to the Commission in the context of Article 56(2), the Board~~ ***The AI Office (AM 2486)*** ~~shall in particular:~~

(***h***) collect and share ***Member State's*** expertise and best practices ~~among Member States~~ (***AM 2483) and to assist Member States national supervisory authorities and the Commission in developing the organizational and technical expertise required for the implementation of this Regulation, including*** ~~***through***~~ ***by means of facilitating the creation and maintenance of a*** ~~***n***~~ ***Union*** ~~***EU***~~ ***pool of experts*** ~~***and exchange of knowledge***~~***; (AM 2496)***

(***i***) ***to examine, on its own initiative or upon the request of its management board or the Commission*** ~~***any***~~ ***question relating to the implementation of*** ~~***covering***~~ ***this Regulation and to issue opinions, recommendations or written contributions*** ~~***on matters with regards to matters relateding to the implementation of this Regulation***~~***including with regard*** ~~***on:***~~ ***to:***

(i) technical specifications or existing standards ~~***regarding the requirements set out in Title III, Chapter 2, the use of harmonised standards or common specifications referred to in Articles 40 and 41, and the benchmarking of AI systems (AM 2416, 2547);***~~ ***(AM 2502);***

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(ii) the Commission's guidelines ~~for national supervisory authorities concerning the application of this Regulation (AM 2479) and guidelines concerning the setting of administrative fines referred to in Article 71~~; (AM 2516)

(iii) codes of conduct and the application thereof, in close cooperation with industry and other relevant stakeholders; (AMs 202, 2479, 2514, 2519, 2531)

(iv) the possible revision of the Regulation, the preparation of the delegated acts, and possible alignments of this Regulation with the legal acts listed in Annex II;

~~possible revisions of this Regulation with regards prohibited practices (AM 2515) and amendments of the Annexes by means of delegated acts in accordance with Article 73, in particular Annex I and Annex III ; (AMs 206, 2415, 2483, 2508, 2537, 2544)~~

~~(v) alignment of this Regulation with the legal acts listed in Annex II and any updates required to those legal acts (AM 2511);~~

(v) trends, such as European global competitiveness in artificial intelligence, the uptake of artificial intelligence in ~~Europe~~ the Union, the development of digital skills, and emerging systemic threats relat~~ed~~ing to artificial intelligence (AM 2411, 2522, 2523, 2533)

(vi) guidance on how ~~the AI Act~~ this Regulation applies to the ever evolving typology of AI value chains, in particular ~~and what~~ on the resulting implications in terms of accountability of all the entities involved ~~will be under the different scenarios based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards~~;

(j) *To issue*

(i) an annual report that includes an evaluation of the implementation of this Regulation, a review of serious incident reports as referred to in Article 62 and the functioning of the database referred to in Article 60 (AM 2411, 2512, 2513), and

(ii) recommendations to the Commission on the categorisation of prohibited practices, , high-risk AI systems referred to in Annex III, the codes of conduct referred to in Article 69, and the application of the general principles outlines in Article 4a (*AMs 200, 2483, 2493, 2489, 2525, 2529, 2541*)

(k) to assist authorities in the establishment and development of regulatory sandboxes and to facilitate cooperation among regulatory sandboxes; (AM 2498, 2499, 2501)

Obtenu par CONTEXTE

(l) to organize meetings with ~~EU~~ Union agencies and governance bodies whose tasks are related to ~~AI~~ artificial intelligence and the implementation of this Regulation;

(m) to organize quarterly consultations with the advisory forum, and, where appropriate, public consultations with other stakeholders, ~~making~~ and to make the results of those consultations public on its website; (AM 2482, 2503, 2504)

(m) to promote public awareness and understanding of the benefits, risks, ~~rules and~~ safeguards and rights and obligations in relation to the use of AI systems; (AMs 204, 2491, 2527, 2534, 2539)

(n) to facilitate the development of common criteria and a shared understanding ~~for~~ among market operators and competent authorities of the relevant concepts provided for in this Regulation; (AM 2510)

(o) to provide ~~particular oversight,~~ monitoring of foundation models and ~~institutionalize~~ to organise a regular dialogue with the developers of ~~fundamental general purpose AI~~ foundation models with regard to ~~about~~ their compliance ~~of fundamental general purpose AI models~~ as well as AI systems that make use of such AI models ~~and about industry best practices for self-governance. Any such meeting shall be open to national supervisory authorities, notified bodies and market surveillance authorities to attend and contribute~~;

~~*(p) provide the secretariat of the management board and of the advisory forum (AM 2455, 2473)*~~

(q) promote AI literacy pursuant to Article 4b.

Article 56c

Accountability, independence, and transparency

1. *The AI Office shall:*

   a. *be accountable to the European Parliament and to the Council in accordance with this Regulation;*

   b. *act independently when ~~performing~~ carrying out its tasks or exercising its powers; and*

   c. *ensure a high level of transparency concerning its activities and develop good administrative practices in that regard. ~~Regulation (EC) No 1049/2001 shall apply to documents held by the AI Office;~~*

   d. *Regulation (EC) No 1049/2001 shall apply to documents held by the AI Office.*

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SECTION 2: Secretariat

Article 57

Secretariat

1. The activities of the secretariat shall be managed by an executive director, who shall be accountable for his or her activities to the management board. Without prejudice to the respective ~~competencies~~ powers of the management board and the Union institutions ~~and the management board,~~ the executive director shall neither seek nor take instructions from any government or from any other body.

2. The executive director ~~may be called upon at any time by the European Parliament or by the Council to~~ shall attend hearings on any matter linked to the AI Office's activities and shall ~~or to~~ report on the ~~carrying out~~ performance of ~~his or her~~ the executive director's duties~~tasks~~ when invited to do so by the European Parliament or the Council.

3. The executive director shall represent the AI Office, including in international fora for cooperation ~~on~~ with regard to artificial intelligence;

4. The secretariat ~~under the supervision of the Executive Director~~ shall provide the management board and the advisory forum with the analytical, administrative and logistical support necessary to fulfil the ~~objectives and~~ tasks of the AI Office, including by:

(a) implementing the decisions, programmes and activities adopted by the management board;

(b) preparing each year the draft single programming document pursuant to Article 57b (1) point (c),the draft budget pursuant to Article 57b (1) point (d), the annual activity report on the AI Office, the draft opinions and positions of the AI Office, and submit them to the management board;

(c) coordinating with international fora for cooperation on artificial intelligence;

~~(f) supporting communication between the members of the Office, its Chair, the Commission and the national supervisory authorities;~~

SECTION 3: Management board

Article 57b

Obtenu par CONTEXTE

Composition of the management board

1. The management board shall be composed of the following members:

(a) one representative of each Member State's national supervisory authority;

(b) one representative from the Commission (AM 2438);

(c) one representative from the European Data Protection Supervisor (EDPS);

(d) one representative from the European Union Agency for Cybersecurity (ENISA);

(e) one representative from the Fundamental Rights Agency (FRA) (AM 2429, 2430, 2431, 2435, 2437).

Each ~~Member State~~ representative of a national supervisory authority shall have one vote. The representatives of the Commission, the EDPS, the ENISA and the FRA shall not have voting rights (186). Each ~~representative~~ member shall have a substitute. The appointment of members and substitute members of the management board shall take into account the need to gender balance. The ~~composition~~ members of the management board and their substitute members shall be made public ~~and take into account gender balance~~.

2. ~~Representatives~~ The members and substitutes members of the management board shall ~~be verified~~ not ~~to~~ hold ~~no~~ conflicting positions or ~~and no~~ commercial interests with regard to ~~in~~ any topic related to the application of the this Regulation ~~at the meetings of the management board~~.

4. The rules for the meetings and voting of the management board and the appointment and removal of the Executive Director shall be laid down in the rules of procedure referred to in Article 57c, point (a).

Article 57c

Functions of the management board

1. The management board shall have the following tasks:

(a) to make strategic decisions on the ~~operation~~ activities of the AI Office and to adopt its rules of procedure by a two-thirds majority of its members;

(b) to implement ~~the~~ its rules of procedure;

(c) to adopt the AI Office's single programming document as well as it annual public report and transmit ~~it~~ both to the European Parliament, to the Council, to the Commission, and to the Court of Auditors;

(d) to adopt the AI Office's budget;

Obtenu par CONTEXTE

(e) to appoint the executive director and, where relevant, to extend or curtail the executive director's ~~his or her~~ term of office or remove him or her from office;

(f) to decide on the establishment of the AI Office's internal structures and, where necessary, the modification of those internal structures necessary for the fulfilment of the AI Office ~~objectives and~~ tasks; (AM 2472)

~~(g) adopt an annual public report about the AI Office's activities and submit it to the European Parliament, to the Council, to the Commission and to the Court of Auditors (AM 211).~~

Article 57d

Chair of the management board (AM 2440)

1. The management board shall elect a Chair and two deputy Chairs from among its voting members, by simple majority. (AMs 192, 2450, 2456, 2459)

2. The term of office of the Chair and of the deputy Chairs shall be four years. The terms of the Chair and of the deputy Chairs~~, may be~~ renewable once (AMs 192, 2450, 2456, 2461).

SECTION 4: Advisory Forum

Article 58

Advisory forum

1. ~~An advisory forum shall be established by the AI Office to advise it in the fulfilment of its tasks~~. The advisory forum shall ~~by~~ provide the AI Office with stakeholder input in matters ~~pertaining~~ relating to this Regulation, in particular with regard to ~~on~~ the tasks set out ~~outlined~~ in Article 56f point (b).

2. The membership of the advisory forum shall represent a ~~have a~~ balanced ~~composition~~ selection of ~~and represent the views of different~~ stakeholders (AM 2465), including industry, start-ups, SMEs, civil society, the social partners and academia (AM 2434, 2457, 2463). The ~~composition~~ membership of the advisory forum shall be balanced with regard to ~~between~~ commercial and non-commercial interests and, within the category of commercial interests, with regards ~~it shall be balanced between large companies and~~ to SMEs and other undertakings.

Obtenu par CONTEXTE

3. *The ~~appointment~~ management board shall appoint ~~and term of~~ the members of the advisory forum ~~shall be decided by the management board~~ in accordance with ~~following the call and~~ the selection procedure established in the AI Office's rules of procedure and taking into account the need for transparency and in accordance with the criteria set out in paragraph 2;*

4. *The term of office of the members of the advisory forum shall be two years, which may be extended by up to no more than four years. ~~and it shall not be renewable more than twice consecutively.~~*

5. *The ~~European Union Agency for Cybersecurity, the~~ European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the Advisory Forum . (AM 2429, 2430, 2431, 2432) The Joint Research Centre shall be permanent member, without voting rights.*

6. *The advisory forum shall draw up its rules of procedure. It shall elect two co-Chairs from among its ~~voting~~ members, in accordance with ~~to the representation~~ criteria set out in paragraph 2. The term of office of the co-Chairs shall be two years, renewable once.*

7. *The advisory forum shall hold ~~regular~~ meetings at least four times a year. The advisory forum ~~can~~ may invite experts and other stakeholders to its meetings (AM 2466). The executive director ~~can~~ may attend, ex officio, the meetings of the advisory forum.*

8. *In fulfilling its role as set out in paragraph 1, the advisory forum ~~can~~ may prepare opinions, recommendations ~~or~~ and written contributions.*

9. *The advisory forum may establish standing or temporary (AM 2447) subgroups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation (AMs 190, 2448, 2449, 2520)*

10. *The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available (AM 2457).*

SECTION 5: European authorities on benchmarking

Article 58a

Benchmarking

The European authorities on benchmarking referred to in Article 15 (1a) and the ~~Board~~ AI Office shall, in close cooperation with international partners, jointly develop cost-effective

Obtenu par CONTEXTE

guidance and capabilities to measure and benchmark aspects of AI systems and AI components, and notably of ~~fundamental general purpose AI~~ foundation models, relevant to the compliance and enforcement of this Regulation based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards.

Obtenu par CONTEXTE

COMP AM 8b

Covering: AMs 739 (RE), 740 (Greens), 741 (RE), 742 (EPP)

Fall: AM 743 (EPP)

(76) In order to ~~facilitate a smooth~~, ***ensure an*** effective and harmonised implementation of this Regulation ~~a European~~***, to achieve a high level of trustworthiness and of protection of health, safety, fundamental rights, the environment, democracy and the rule of law ~~and the Union values enshrined in Article 2 TEU~~ across the Union with regards to*** Artificial Intelligence ***systems, to actively support ~~Member States~~,national supervisory ~~competent~~ authorities, (AM 741), 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*** ~~Board~~ should be established. The ***AI Office should have legal personality, should act in full independence, should be responsible for a number of advisory and coordination ~~enforcement~~ tasks (AM 740), and should be adequately funded and staffed. Member States should provide the strategic direction and control of the AI Office through the management*** ~~B~~***b***oard ***of the AI Office, alongside the Commission, the EDPS, the FRA, and ENISA. An executive director*** should be responsible ***for the coordination of the AI Office's operations and for*** ~~a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to~~ the implementation of ***its work programme. Stakeholders (AM 742) should formally participate in the work of the AI Office through an advisory forum that should ensure varied and balanced stakeholder representation and should advise the AI Office on matters pertaining to*** ~~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~~. ***(AM 739)***

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COMP AM XX

Covering: 212 (Rapp.), 213 (Rapp.), 214 (Rapp.), 215 (Rapp.), 216 (Rapp.), 217 (Rapp.), 218 (Rapp.), 219 (Rapp.), 2556 (S&D), 2560 (Greens), 2562 (EPP), 2566 (EPP), 2568 (Left), 2569 (S&D), 2570 (EPP), 2571 (Greens), 2572 (RE), 2573 (EPP), 2574 (ECR), 2575 (ECR), 2576 (EPP), 2580 (Left), 2581 (RE), 2583 (S&D), 2584 (RE), 2585 (EPP), 2586 (Greens), 2587 (ECR), 2588 (S&D), 2589 (RE), 2591 (EPP), 2593 (RE), 2595 (S&D), 2596 (EPP), 2597 (RE), 2598 (Greens), 2601 (S&D), 2602 (S&D)

Fall: 2557 (EPP), 2558 (EPP), 2559 (EPP), 2561 (S&D), 2563 (EPP), 2564 (Greens), 2565 (ID), 2567 (ID), 2577 (Greens), 2578 (ECR), 2579 (ID), 2582 (EPP), 2590 (Greens), 2592 (EPP), 2594 (Left), 2599 (Greens), 2600 (S&D)*Article 59*
Designation of national ***supervisory*** *authorities*

Orientation CONTEXTE

1. ~~National competent authorities shall be established or designated by~~ ~~e~~ ***E***ach Member State ***shall designate one*** ~~for the purpose of ensuring the application, and implementation, and enforcement (AM 2560)~~ ~~of this Regulation.~~ national ***supervisory authority, which*** ~~competent authorities~~ shall be organised so as to safeguard the objectivity and impartiality of ~~their~~ ***its*** activities and tasks ***by [3 months after the entry into force of this Regulation]***. ***(JURI 131)***

2. ~~Each Member State shall designate a **single**~~ ***The*** national supervisory authority ~~among the national competent authorities by~~ ***shall ensure the application and implementation of this Regulation. With regard to high-risk AI systems, related to products to which legal acts listed in Annex II apply, the*** competent authorities ***designated under those legal acts shall continue to lead the administrative procedures. However, to the extent a case involves aspects exclusively covered by this Regulation, those competent authorities shall be bound by the measures related to those aspects issued by the national supervisory authority designated under this Regulation.*** The national supervisory authority shall act as ~~notifying authority and~~ market surveillance authority. (***JURI 132)***

3. Member States shall ***make publicly available and communicate to the AI Office and the (AMs 215, 2568)*** Commission ***the~~ir~~ national supervisory authority and information on how it can be contacted, by...[three months after the entry into force of this Regulation] (AM 215). The national supervisory authority shall act as single point of contact for this Regulation and should be contactable though electronic communications means (AMs 2587, 2591, JURI 133).***

4. Member States shall ensure that ***the*** national ~~competent authorities are~~ ***supervisory authority is*** provided with adequate ***technical (AM 216, 2569, 2571, 2572),*** financial and human resources***, and infrastructure (AMs 216, 2569)*** to fulfil their tasks ***effectively (AM 2571)*** under this Regulation. In particular, ***the national supervisory authority*** shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of artificial intelligence technologies, data and data computing, ***personal data protection, cybersecurity, competition law, (AM 216, 2569, 2570, 2571, JURI 134)*** fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. ***Member States shall assess and, if deemed necessary, update competence and resource requirements referred to in this paragraph on an annual basis. (AM 216, 2569)***

4a. ***Each national supervisory authority shall exercise their powers and carry out their duties independently, impartially and without bias. ~~act independently in performing its tasks and exercising its powers in accordance with this Regulation.~~ The members of each national supervisory authority , in the performance of their tasks and exercise of their powers under this Regulation, shall neither seek nor take instructions from anybody and (AMs 214, 2595, 2598).***

shall refrain from any action incompatible with their duties.. (AM 2595)

4c. ***National supervisory authorities shall satisfy the minimum cybersecurity requirements set out for public administration entities identified as operators of***

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essential services pursuant to Directive XXXX/XX on measures for a high common level of cybersecurity across the Union (NIS 2), repealing Directive (EU) 2016/1148. (AMs 2573, 2574, JURI 135)

4 d. ***When performing their tasks, the national supervisory authority shall act in compliance with the confidentiality obligations set out in Article 70. (AMs 2575, 2576, JURI 136)***

5. Member States shall report to the ***the (AM 2580)*** Commission on an annual basis on the status of the financial and human resources of the***ir*** national ***supervisory authority*** ~~competent authorities~~ ***(JURI 137)*** with an assessment of ***its*** adequacy. The Commission shall transmit that information to the ***AI Office (AM 2581)*** for discussion and possible recommendations.

7. National ~~competent~~ ***supervisory (AM JURI 139)*** authorities may provide guidance and advice on the implementation of this Regulation, including to ~~small-scale providers~~ ***SMEs and start-ups (AM JURI 139), taking into account the AI Office or the Commission's guidance and advice (AM 2592)***. Whenever ***the*** national ~~competent~~ ***supervisory*** authorit***y***~~ies~~ intend to provide guidance and advice with regard to an AI system in areas covered by other Union legislation, the ***guidance shall be drafted in consultation with the (AM 2588)*** competent national authorities under that Union legislation ~~shall be consulted~~, as appropriate. ~~Member States may also establish one central contact point for communication with operators~~

8. When Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision ***and coordination (AM 2593)***.

Article 59a

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

1. ***Each national supervisory authority shall perform its tasks and powers conferred on in accordance with this Regulation on the territory of its own Member State.***

2. ***In the event of a case involving two or more national supervisory authorities, the national supervisory authority of the Member State where the infringement took place shall be considered the lead supervisory authority.***

3. ***In the cases referred to in paragraph 2, the relevant supervisory authorities shall cooperate and exchange all relevant information in due time. National supervisory authorities shall cooperate in order to reach a consensus.***

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

Obtenu par CONTEXTE

~~*5. The AI Office shall, within three months of receipt of the notification referred to in paragraph 4, issue a decision to the national supervisory authorities (AMs 219, 2596, 2597, 2601, 2602) in accordance with the procedure laid down in Article 66.*~~

COMP AM XX

Covers: 220 (Rapp), 221 (Rapp), 222 (Rapp), 223 (Rapp), 224 (Rapp), 225 (Rapp), 2608 (The Left), 2609 (S&D), 2612 (The Left), 2613 (S&D), 2615 (RE), 2617 (S&D), 2618 (Greens), 2621 (Greens)2622 (S&D), 2623 (Greens), 2625 (The Left), 2625 (S&D), 2627 (RE), 2633 (S&D), 2634 (Greens), 2637 (The Left), TRAN 117
Falls: 2606 (EPP), 2607 (Greens), 2610 (The Left), 2611 (Greens), 2616 (EPP), 2619 (EPP), 2620 (The Left), 2626 (The Left), 2628 (The Left), 2629 (S&D), 2630 (ECR), 2631 (EPP), 2632 (The Left), 2635 (ECR), 2636 (EPP), 2638 (The Left), TRAN 118, 258 (Rapp), 259 (Rapp), 260 (Rapp), 261 (Rapp), 262 (Rapp), 263 (Rapp), 264 (Rapp), 265 (Rapp), 266 (Rapp), 267 (Rapp), 2775 (S&D)
Parks: 2614 (The Left) - linked to GPAI,

TITLE VII

EU DATABASE FOR ~~STAND-ALONE~~ HIGH-RISK AI SYSTEMS *(AMs 2608, 2609)*

Article 60
EU database for ~~stand-alone~~ high-risk AI systems ***(AMs 2612, 2613)***

1. The Commission shall, in collaboration with the Member States, set up and maintain a ***public (AM 1618)*** EU database containing information referred to in paragraph***s*** 2 ***and 2a (AM 220)*** concerning high-risk AI systems referred to in ~~***one of the areas***~~

Obtenu par CONTEXTE

~~*listed in Annex III (AM 2615)*~~ Article 6(2) which are registered in accordance with Article 51*.(AMs 220, 2615, 2617)*

2. The data listed in Annex VIII*, Section A, (AM 221)* shall be entered into the EU database by the providers.

2a. The data listed in Annex VIII, Section B, shall be entered into the EU database by the deployers who are or who act on behalf of public authorities or Union institutions, bodies, offices or agencies and by deployers who are undertakings referred to in Article 51(1a) and (1b).

3. Information contained in the EU database shall be *freely available ~~accessible~~* (*AMs 2623, 2624)* to the public*, user-friendly and accessible, easily navigable and machine-readable containing structured digital data based on a standardised protocol*. *(AM 223, 2623,, TRAN 117)*

4. The EU database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider *or the deployer which is a public authority or Union institution, body, office or agency or a deployer acting on their behalf or a deployer which is an undertaking referred to in Article 51(1a)(b) and (1b). (AMs 224, 2627)*

5. The Commission shall be the controller of the EU database. It shall also ensure to providers *and deployers* adequate technical and administrative support. *(AMs 225, 2633, 2634)*

The database shall comply with the accessibility requirements of Annex I to Directive 2019/882 (AM 2637)

COMP AM XX

Covers: 226 (Rapp), 2648 (RE), 2640 (The Left), 2641 (S&D), 2642 (Greens, 2643 (RE), 2644 (EPP), TRAN 119

Falls: 2639 (EPP), 2645 (ID), 2646 (ECR), 2647 (ID)

Obtenu par CONTEXTE

TITLE VIII

POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE

CHAPTER 1

POST-MARKET MONITORING

Article 61
Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system.

2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by ~~users~~ ***deployers*** or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Title III, Chapter 2. ***Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems , including other devices and software, taking into account the rules applicable from areas such as data protection, intellectual property rights and competition law. (AMs 2640, 2641, 2642, 2643, 2644, TRAN 119)***

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan ***by [12 months following the entry into force]. (AMs 226, 2648)***

4. For high-risk AI systems covered by the legal acts referred to in Annex II, where a post-market monitoring system and plan is already established under that legislation, the elements described in paragraphs 1, 2 and 3 shall be integrated into that system and plan as appropriate.

   The first subparagraph shall also apply to high-risk AI systems referred to in point 5(b) of Annex III placed on the market or put into service by credit institutions regulated by Directive 2013/36/EU.

COMP AM XX

Covers: 227 (Rapp), 228 (Rapp), 229 (Rapp), 230 (Rapp), 231 (Rapp), 232 (Rapp), 2651 (S&D), 2652 (S&D), 2654 (The Left), 2655 (RE), 2656 (Greens), 2657 (RE), 2658 (Greens),

Obtenu par CONTEXTE

2660 (S&D), 2661 (The Left), 2662 (EPP), 2664 (RE), 2667 (S&D), 2668 (RE), 2669 (EPP), 2670 (S&D), 2673 (RE),

Falls: 2649 (EPP), 2650 (EPP), 2653 (EPP), 2659 (ID), 2663 (EPP), 2665 (EPP), 2666 (Greens), 2671 (Greens), 2672 (EPP), ENVI 99

Parked: 2652 (S&D) - linked to GPAI, 2661 (The Left), -

CHAPTER 2

SHARING OF INFORMATION ON INCIDENTS AND MALFUNCTIONING

Article 62
Reporting of serious incidents

1. Providers ***and, where deployers have identified a serious incident, deployers (AMs 227, 2651, 2652, 2654, 2655)*** of high-risk AI systems placed on the Union market shall report any serious incident of those systems which constitutes a breach of obligations under Union law intended to protect fundamental rights to the ~~market surveillance authorities~~ ***national supervisory authority*** of the Member States where that incident or breach occurred.

   Such notification shall be made ~~immediately~~ ***without undue delay (AM 2657, 2662)***after the provider***, or where applicable the deployer, (AM 228)*** has established a causal link between the AI system and the incident or the reasonable likelihood of such a link, and, in any event, not later than ~~15 days~~ ***72 hours (AM 228, 2657, 2658, 2659, 2660, 2661, 2662)*** after the providers***, or, where applicable, the deployer (AM 228)*** becomes aware of the serious incident.

1a. Upon establishing a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, providers shall take appropriate corrective actions pursuant to Article 21. (AM 229, 2668)

2. Upon receiving a notification related to a breach of obligations under Union law intended to protect fundamental rights, the ~~market surveillance authority~~ ***national supervisory authority*** shall inform the national public authorities or bodies referred to in Article 64(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1. That guidance shall be issued ~~12 months~~ ***by*** ~~after~~ ***[***the entry into force of this Regulation***]***~~, at the latest~~ ***and shall be assessed regularly . (AM 230)***

2a. The national supervisory authority shall take appropriate measures within 7 days from the date it received the notification referred to in paragraph 1. Where the infringement takes place or is likely to take place in other Member States, the national supervisory authority shall notify the AI Office and the relevant national supervisory authorities of these Member State. (AM 2667)

Obtenu par CONTEXTE

3. For high-risk AI systems referred to Annex III ***that*** are placed on the market or put into service by providers that are ***subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this*** Regulation , the notification of serious incidents ~~shall be limited to those that that~~ constitut***ing*** a breach of ***fundamental rights protected*** ~~obligations~~ under Union law ~~intended to protect fundamental rights~~ ***) shall be transferred to the national supervisory authority***. ***(AM 2669)*** ~~***In that case, the receiving authorities competent under those laws shall forward the received report notification to the national supervisory authority (AMs 2663, 2664)***~~

3a. National supervisory authorities shall on an annual basis notify the AI Office of the serious incidents reported to them in accordance with this Article. (AM 232, 2673)

Related definition of serious incident

(44) 'serious incident' means any incident ***or malfunctioning of an AI system*** that directly or indirectly leads, might have led or might lead to any of the following:

(a) the death of a person or serious damage to a person's health, to property or the environment,

(b) a serious and irreversible disruption of the management and operation of critical infrastructure.

(ba) a breach of fundamental rights protected under Union law; (AMs 1090, 1094, 1095, 1097)

Obtenu par CONTEXTE

COMP AM XX

Covers: 233 (Rapp), 2674 (RE), 2675 (EPP), 2677 (S&D), 2678 (S&D), 2703 (The Left)

Falls: 2676 (RE), 2681 (ECR), 2767 (ID)

Parked: 2708 (S&D), - linked to Article 4a

CHAPTER 3

ENFORCEMENT

Article 63
Market surveillance and control of AI systems in the Union market

1. Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. However, for the purpose of the effective enforcement of this Regulation:

   (a) any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Title III, Chapter 3 of this Regulation;

   (b) any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI systems falling within the scope of this Regulation.

   (c) the national supervisory authorities shall act as market surveillance authorities under this Regulation and have the same powers and obligations as market surveillance authorities under Regulation (EU) 2019/1020.

2. The national supervisory authority shall report to the Commission ***and the AI Office*** ~~on a regular basis~~ ***annually (AM 233, 2674)*** the outcomes of relevant market surveillance activities. The national supervisory authority shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules.

3. For high-risk AI systems, related to products to which legal acts listed in Annex II, section A apply, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts.

3 a. For the purpose of ensuring effective enforcement of this Regulation, national supervisory authorities may:

(a) carry out unannounced on-site and remote inspections of high-risk AI systems;

(b) acquire samples related to high-risk AI systems, including through remote inspections, to reverse-engineer the AI systems and to acquire evidence to identify non-compliance. (AMs 2675, 2703)

Obtenu par CONTEXTE

4. For AI systems placed on the market, put into service or used by financial institutions regulated by Union legislation on financial services, the market surveillance authority for the purposes of this Regulation shall be the relevant authority responsible for the financial supervision of those institutions under that legislation.

5. For AI systems ~~listed in point 1(a) insofar as the systems~~ ***that*** are used for law enforcement purposes~~, points 6 and 7 of Annex III,~~ Member States shall designate as market surveillance authorities for the purposes of this Regulation ~~either~~ the competent data protection supervisory authorities under Directive (EU) 2016/680 ***(AMs 2677, 2678),*** ~~or Regulation 2016/679 or the national competent authorities supervising the activities of the law enforcement, immigration or asylum authorities putting into service or using these systems.~~

6. Where Union institutions, agencies and bodies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority.

7. ~~market surveillance authorities~~ ***National supervisory authorities*** designated under this Regulation ***shall coordinate with*** other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex II or other Union legislation that might be relevant for the high-risk AI systems referred to in Annex III.

Obtenu par CONTEXTE

Obtenu par CONTEXTE

COMP AM XX

Covers: 2679 (RE), 2680 (EPP), 2682 (S&D), 2683 (EPP), 2684 (EPP), 2686 (EPP), 2688 (RE), 2689 (RE), 2699 (EPP),

Fall: 234 (Rapp), 235 (Rapp), 236 (Rapp), 237 (Rapp), 2681 (ECR), 2684 (EPP), 2685 (Greens); 2687 (EPP), 2691 (ECR), 2692 (EPP), 2693 (EPP), 2694 (EPP), 2695 (Greens), 2697 (S&D), 2698 (S&D), 2700 (S&D), 2701 (Greens), 2702 (EPP),

Parked: 2682 (S&D), 2690 (S&D), 2696 (RE) - fundamental rights impact assessment,

Article 64
Access to data and documentation

1. ~~Access to data and documentation~~ ***I***n the context of their activities, ***and upon reasoned request (AM 2683)*** the~~market surveillance authorities~~ ***national supervisory authority (AM 2682),*** shall be granted full access to the training, validation and testing datasets used by the provider, ***or, where relevant, the deployer, that are relevant and strictly necessary for the purpose of its request (AMs 234, 2679, 2680, 2684)*** ~~including~~ through ~~application programming interfaces ('API') or other~~ appropriate technical means and tools. ~~enabling remote access~~.

2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2***, after all other reasonable ways to verify conformity including paragraph 1 have been exhausted and have proven to be insufficient, (AMs 2688, 2689)*** and upon a reasoned request, the ***national supervisory authority*** ~~market surveillance authorities~~ shall be granted access to the ~~source code~~ ***training models*** of the AI system***, including its relevant model parameters***. ***All information in line with Article 70 obtained shall be treated as confidential information and shall be subject to existing Union law on the protection of intellectual property and trade secrets and shall be deleted upon the completion of the investigation for which the information was requested***. ***(AM 2688)***

2a. ***Paragraph 1 and 2 are without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020.***3.
National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of the competences under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the ***national supervisory authority*** of the Member State concerned of any such request.

4. By 3 months after the entering into force of this Regulation, each Member State shall identify the public authorities or bodies referred to in paragraph 3 and make a list publicly available on the website of the national supervisory authority. ***National***

Obtenu par contexte

supervisory authorities shall notify the list to the Commission, ***the AI Office,*** and all other ***national supervisory authorities*** and keep the list up to date. ***The Commission shall publish in a dedicated website the list of all the competent authorities designated by the Member States in accordance with this article. (AM 2699)***

5. Where the documentation referred to in paragraph 3 is insufficient to ascertain whether a breach of obligations under Union law intended to protect fundamental rights has occurred, the public authority or body referred to ***in*** paragraph 3 may make a reasoned request to the ~~market surveillance authority~~ ***national supervisory authority (AM 2700),*** to organise testing of the high-risk AI system through technical means. The ~~market surveillance authority~~***national supervisory authority (AM 2700)*** shall organise the testing with the close involvement of the requesting public authority or body within reasonable time following the request.

6. Any information and documentation obtained by the national public authorities or bodies referred to in paragraph 3 pursuant to the provisions of this Article shall be treated in compliance with the confidentiality obligations set out in Article 70.

Obtenu par CONTEXTE

COMP AM XX

Covers: 238 (Rapp), 239 (Rapp), 240 (Rapp), 242 (Rapp), 243 (Rapp), 244 (Rapp), 245 (Rapp), 246 (Rapp), 247 (Rapp), 2705 (S&D), 2706 (The Left), 2708 (S&D), 2709 (RE), 2712 (S&D - RE), 2713 (The Left), 2715 (RE), 2717 (S&D), 2719 (S&D), 2720 (S&D), 2721 (S&D), 2722 (RE), 2723 (RE), 2724 (S&D), 2724 (S&D), 2725 (S&D), 2728 (RE), 2729 (RE), 2730 (RE), 2731 (RE), 2733 (S&D), 2735 (RE), 2737 (RE), ENVI 100, TRAN 120

Fall: 241 (Rapp), 2704 (S&D), 2707 (ID), 2710 (S&D - RE), 2711 (The Left), 2714 (S&D), 2716 (The Left), 2718 (ID), 2726 (RE), 2727 (RE), 2732 (ID), 2734 (ID), 2736 (S&D),

Parked: 2719 (S&D), - linked to common principles on AI

Article 65

Procedure for dealing with AI systems presenting a risk at national level

1. AI systems presenting a risk shall be understood as ~~a product presenting a risk defined in Articele 3 point 19 of Regulation (EU) 2019/1020 insofar as risks to the health or safety or to the protection of~~ ***an AI system having the potential to affect adversely health and safety,*** fundamental rights of persons ***in general, including in the workplace, protection of consumers, the environment, public security, or democracy or the rule of law(AM 238, ENVI 100, TRAN 120) and other public interests, that are protected by the applicable Union harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the system*** are concerned***, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements. (AM 1098)***

2. Where the ~~market surveillance authority~~ ***national supervisory authority (AM 2719)*** of a Member State has sufficient reasons to consider that an AI system presents a risk as referred to in paragraph 1, ~~they~~ ***it*** shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. When risks to ~~the protection of~~ ***(AM 2715)*** fundamental rights are present, the ~~market surveillance authority~~ ***national supervisory authority*** shall also ***immediately (AM 239)*** inform ***and fully cooperate with (AM 239)*** the relevant national public authorities or bodies referred to in Article 64(3). ***Where there is sufficient reason to consider that that an AI system exploits the vulnerabilities of vulnerable groups or violates their rights intentionally or unintentionally, the national supervisory authority shall have the duty to investigate the design goals, data inputs, model selection, implementation and outcomes of the AI system (AMs 2712, 2713)*** The relevant operators shall cooperate as necessary with the ~~market surveillance authorities~~ ***national supervisory authority*** and the other national public authorities or bodies referred to in Article 64(3).

   Where, in the course of that evaluation, the ~~market surveillance authority~~ ***national supervisory authority or, where relevant, the national public authority referred to in Article 64(3) (AM 240)*** finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without delay

Obtenu par CONTEXTE

require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe ***and in any case no later than 15 working days or as provided for in the relevant Union harmonisation legislation as applicable (AMs 2717, 2720)***.

The ~~market surveillance authority~~ ***national supervisory authority*** shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph.

3. Where the ~~market surveillance authority~~ ***national supervisory authority (AM 2721)*** considers that non-compliance is not restricted to its national territory, it shall inform the Commission***, the AI Office (AM 2723)*** and the ***national supervisory authority of the*** other Member States ***without undue delay (AM 2722)*** of the results of the evaluation and of the actions which it has required the operator to take.

4. The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the market throughout the Union.

5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the ~~market surveillance authority~~ ***national supervisory authority (AM 2724)*** shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market ***or put into service (AM 242)***, to withdraw the ~~product~~ ***AI system (AM 242)*** from that market or to recall it. That authority shall ***immediately (AMs 2724, 2725)*** inform the Commission***, the AI Office (AM 242)*** and the ***national supervisory authority of the*** other Member States ~~without delay,~~ ***(AMs 2724, 2725)*** of those measures.

6. The information referred to in paragraph 5 shall include all available details, in particular the data necessary for the identification of the non-compliant AI system, the origin of the AI system ***and the supply chain (AM 243)***, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the ~~market surveillance authorities~~ ***national supervisory authority*** shall indicate whether the non-compliance is due to one or more of the following:

   (a) a failure of the ***high-risk (AM 2729)*** AI system to meet requirements set out ~~in Title III, Chapter 2~~ ***this Regulation***; ***(AM 244, 2728)***

   (b) shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity.

   (ba) non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5; (AM 2730)

   (bb) non-compliance with provisions set out in Article 52 (AM 2731)

7. The ~~market surveillance authorities~~ ***national supervisory authorities (AM 2733)*** of the Member States other than the ~~market surveillance~~ ***national supervisory*** authority of the Member State initiating the procedure shall without delay inform the Commission***, the AI Office (AM 245)*** and the other Member States of any measures

Obtenu par CONTEXTE

adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

8. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either ***a national supervisory authority of*** a Member State or the Commission in respect of a provisional measure taken by a ***national supervisory authority of another*** Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. ***The period referred to in the first sentence of this paragraph shall be reduced to 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5. (AM 2735)***

9. The ~~market surveillance authorities~~ ***national supervisory authorities*** of all Member States shall ensure that appropriate restrictive measures are taken in respect of the ~~product~~ ***AI system (AMs 246, 2737)*** concerned, such as withdrawal of the ~~product~~ ***AI system (AMs 246, 2737)*** from their market, without delay.

9a. National supervisory authorities shall annually report to the AI Office about the use of prohibited practices that occurred during that year and about the measures taken to eliminate or mitigate the risks in accordance with this Article. (AM 247)

Obtenu par CONTEXTE

COMP AM

Covers: 248 (Rapp), 249 (Rapp), 2739 (RE), 2741 (Greens),

Fall: 2738 (ID), 2740 (The Left), 2742 (Greens), 2743 (The Left), 2744 (EPP)

Parked:

Article 66
Union safeguard procedure

1. Where, within three months of receipt of the notification referred to in Article 65(5), ***or 30 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5, (AM 2739)*** objections are raised by ***the national supervisory authority of*** a Member State against a measure taken by another ***national supervisory authority***, ~~***or in cases referred to in Article 59a(4),***~~ or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the ***national supervisory authority of the*** relevant Member State and operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within ~~9~~ ***three (AM 248)*** months***, or 60 days in the case of non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5, starting (AM 2739)*** from the notification referred to in Article 65(5) and notify such decision to ***the national supervisory authority of*** the Member State concerned. ***The Commission shall also inform all other national supervisory authorities of such decision. (AM 2739)***

2. If the national measure is considered justified, all ***national supervisory authorities designated under this Regulation*** ~~Member States~~ shall take the measures necessary to ensure that the non-compliant AI system is withdrawn from their market ***without delay (AM 249)***, and shall inform the Commission ***and the AI Office (AM 249)*** accordingly. If the national measure is considered unjustified, the ***national supervisory authority of the*** Member State concerned shall withdraw the measure.

3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

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Obtenu par CONTEXTE

COMP AM

Covers: 250 (Rapp), 252 (Rapp), 2748 (RE), 2749 (S&D), 2755 (RE), 2758 (RE), 2762 (RE), 2764 (Greens), ENVI 101, TRAN 121

Fall: 251 (Rapp), 2745 (S&D), 2746 (EPP), 2747 (S&D), 2750 (S&D), 2751 (RE), 2752 (EPP), 2753 (RE), 2754 (S&D), 2756 (Greens), 2757 (ID), 2765 (S&D), 2770 (S&D),

Parked: 2759 (S&D), 2760 (Greens), 2761 (S&D), 2763 (Greens), - linked to governance

Article 66 a
Joint investigations

1. Where a national supervisory authority has reasons to suspect that the infringement by a provider or a deployer of a high-risk AI system to this Regulation amount to a widespread infringement, a widespread infringement with a Union dimension, or affects or is likely affect at least 45 million individuals , in more than one Member State, that national supervisory authority shall inform the AI Office and may request the national supervisory authorities of the Member States where such infringement took place to start a joint investigation. The AI Office shall provide central coordination to the joint investigation. Investigation powers shall remain within the competence of the national supervisory authorities.

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Related definitions

(44d) 'widespread infringement' means:

(a) any act or omission contrary to Union law that protects the interests of individuals, that has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State, in which:

(i) the act or omission originated or took place;

(ii) the provider concerned, or, where applicable, its authorised representative is established; or,

(iii) the deployer is established, when the infringement is committed by the deployer; (b) any acts or omissions contrary to Union law that protects the interests of individuals, that have done, do or are likely to do harm to the collective interests of individuals and that have common features, including the same unlawful practice, the same interest being infringed and that are occurring concurrently, committed by the same operator, in at least three Member States; (AM 74)

(44e) 'widespread infringement with a Union dimension' means a widespread infringement that has harmed or is likely to harm the collective interests of individuals in at least two-thirds of the Member States, accounting, together, for at least two-thirds of the population of the Union. (AM 75)

Obtenu par CONTEXTE

Article 67
Compliant AI systems which present a risk

1. Where, having performed an evaluation under Article 65, ***in full cooperation with the relevant national public authority referred to in Article 64(3), (AM 250, 2749)*** the ~~market surveillance authority~~ ***national supervisory authority*** of a Member State finds that although an AI system is in compliance with this Regulation, it presents a ***serious*** risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights***, or the environment (AM 2749, ENVI 101, TRAN 121) or the democracy and rule of law (AM 250)*** or to other aspects of public interest protection , it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk~~., to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.~~

2. The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market throughout the Union within the timeline prescribed by the ***national supervisory authority*** ~~market surveillance~~ authority of the Member State referred to in paragraph 1.

2a. Where the provider or other relevant operators fail to take corrective action as referred to in paragraph 2 and the AI system continues to present a risk as referred to in paragraph 1, the national supervisory authority may require the relevant operator to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk. (AMs 2748, 2753).

3. The ***national supervisory authority*** shall immediately inform the Commission***, the AI Office (AM 251, 2755)*** and the other ***national supervisory authorities***. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission ***in consultation with the AI Office*** shall without delay enter into consultation with the ***national supervisory authorities concerned (AM 2758)*** and the relevant operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the ~~Commission~~ ***AI Office*** shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

5. The Commission ***in consultation with the AI Office*** shall ***immediately communicate*** ~~address~~ its decision to the ***national supervisory authorities of the*** Member States ***concerned and to the relevant operators***. ***It shall also*** ~~immediately communicate~~ ***inform the decision to*** ~~the~~ ***all other national supervisory authorities~~nd to the relevant operators~~. (AM 252, 2761, 2762)***

5 a. The Commission AI Office shall adopt guidelines to help national competent authorities to identify and rectify, where necessary, similar problems arising in other AI systems. (AM 2764)

Obtenu par CONTEXTE

COMP AM XX

Covers: 253 (Rapp), 254 (Rapp), 255 (Rapp), 256 (Rapp), 257 (Rapp), 2766 (EPP), 2768 (EPP), 2769 (RE),

Fall: 2767 (ID),

Parked:

Article 68
Formal non-compliance

1. Where the ~~market surveillance~~ ***national supervisory*** authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned:

   (a) the ~~conformity~~ ***CE (AM 253)*** marking has been affixed in violation of Article 49;

   (b) the ~~conformity~~ ***CE (AM 254, 2766)*** marking has not been affixed;

   (c) the EU declaration of conformity has not been drawn up;

   (d) the EU declaration of conformity has not been drawn up correctly;

   (e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;

   (ea) the technical documentation is not available; (AM 255)

   (eb) the registration in the EU database has not been carried out. (AM 256)

   (ec) where applicable, the authorised representative has not been appointed.

2. Where the non-compliance referred to in paragraph 1 persists, the ***national supervisory authority of the*** Member State concerned shall take ~~all~~ appropriate ***and proportionate (AM 2768, 2769)*** measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market ***without delay. The national supervisory authority of the Member State concerned shall immediately inform the AI Office of the non-compliance and the measures taken. (AM 257)***

Obtenu par CONTEXTE

COMP AM XX

Covers: 268 (Rapp), 269 (Rapp), 270 (Rapp), 2771 (Greens), 2772 (RE), 2773 (S&D), 2776 (The Left), 2777 (EPP), 2779 (RE), 2780 (Greens), 2785 (S&D),

Falls: 2774 (EPP), 2778 (S&D), 2781 (S&D), 2784 (Greens), 2783 (S&D), 2999 (S&D)

Parked: 2782 (Greens)

Obtenu par CONTEXTE

Chapter 3b Remedies (AM 268)

~~Article 68a~~
~~Right to lodge a complaint~~

~~1. Natural persons or groups of natural persons affected by an AI system falling within the scope of this Regulation shall have the right to lodge a complaint against the providers or deployers of such AI system with the national supervisory authority of the Member State where they have their habitual place of residence or place of work or where the alleged infringement took place, if they consider that their health, safety, or fundamental rights have been breached.~~

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

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

~~4. The national supervisory authority shall take a decision on the complaint, including the possibility of a judicial remedy pursuant to Article 68b, without delay and no later than six months after the date on which the complaint was lodged. (AM 269, 2771, 2772, 2773, 2776, 2777, JURI 148)~~

~~Article 68b~~
~~Right to an effective judicial remedy against a national supervisory authority~~

~~1. Without prejudice to any other administrative or non-judicial remedy, natural persons and legal persons or groups of natural or legal persons shall have the right to an effective judicial or non-judicial remedy, including repair, replacement, price reduction, contract termination, reimbursement of the price paid or compensation for material and immaterial damages against~~

~~*a legally binding decision of a national supervisory authority concerning them that infringes their rights.*~~

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

~~*3. Proceedings against a national supervisory authority shall be brought before the courts of the Member State where that authority is established. (AM 270, 2779, 2780, JURI 149)*~~

Article 68a

Right to lodge a complaint with a national supervisory authority

1. Without prejudice to any other administrative or judicial remedy, every natural persons or groups of natural persons shall have the right to lodge a complaint with a national supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if they consider that the AI system relating to him or her infringes this Regulation.

2. The national supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy pursuant to Article 78.

Article 68b

Right to an effective judicial remedy against a supervisory authority

1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a national supervisory authority concerning them.

2. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to a an effective judicial remedy where the national supervisory authority which is competent pursuant to Articles 59 does not handle a complaint or does not inform the data subject within three months on the progress or outcome of the complaint lodged pursuant to Article 68a.

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

4. Where proceedings are brought against a decision of a national supervisory authority which was preceded by an opinion or a decision of the Commission in the

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union safeguard procedure, the supervisory authority shall forward that opinion or decision to the court.

Article 68c
A right to explanation of individual decision-making

1. *Any affected person subject to a decision which is taken by the ~~provider or user~~ deployer on the basis of the output from an high-risk AI system ~~falling within the scope of this Regulation and~~ which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely impact their health, safety, fundamental rights, socio-economic well-being or any other of the rights deriving from the obligations laid down in this Regulation, ~~on an affected person, or which similarly significantly affects that person~~ shall have the right to request from the deployer clear and meaningful explanation pursuant to Article 13(1) on the role of the AI system in the decision-making procedure, the main parameters of the decision taken and the related input data. ~~receive from the provider or the deployer, at the time when the decision is communicated, a clear and meaningful explanation pursuant to Article 13(1) on of the role of the AI system in the decision-making procedure, the main parameters of the decision taken and the related input data. be accompanied by a meaningful explanation of:~~*

   ~~(a) the role of the AI system in the decision-making process;~~

   ~~(b) the logic involved, the main parameters of the decision-making, and their relative weight; and~~

   ~~(c) the input data relating to the affected person and each of the main parameters on the basis of which the decision was made.~~

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

~~2. For the purpose of Paragraph 1, it shall be prohibited for the law enforcement authorities or the judiciary in the Union to use AI systems that are considered closed or labelled as proprietary by the providers or the distributors;~~

2. *Paragraph 1 shall not apply to the use of AI systems:for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law are provided in so far as such exception or restrictions respect the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society.*

Obtenu par CONTEXTE

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

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

3. This Article shall apply without prejudice to Articles 13, 14, 15, and 22 of the Regulation 2016/679

Article 68d

Representative actions

The following is added to Annex I of Directive (EU) 2020/1828 on Representative actions for the protection of the collective interests of consumers: "Regulation xxxx/xxxx of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts". (AM 2783, 2999, JURI 151)

Article 68 d

Reporting of breaches and protection of reporting persons

Directive (EU) 2019/1937 of the European Parliament and of the Council shall apply to the reporting of breaches of this Regulation and the protection of persons reporting such breaches. (AM 2785)

Obtenu par CONTEXTE

RECITAL

Covers AMs: 39 (Rapp); 40 (Rapp); 44 (Rapp); 45 (Rapp); 46 (Rapp); 745 (S&D); 746 (S&D); 748 (Greens); 751 (Greens); 755 (EPP), 757 (RE), 758 (S&D); 759 (RE); 761 (Greens); 763 (EPP); 764 (S&D); 765 (S&D); 766 (The Left); 767 (S&D); 768 (The Left)

Falls AMs: 41 (Rapp); 42 (Rapp); 43 (Rapp); 744 (Greens); 747 (ID); 749 (EPP); 750 (Greens), 752 (ID); 752 (EPP); 754 (Greens), 756 (S&D); 757 (RE); 760 (Greens); 762 (Greens);

Parked:

(77) ***Each*** 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~~ ***a*** national ~~competent authorities~~ ***supervisory authority (AM 745)*** for the purpose of supervising the application and implementation of this Regulation. ***It should also represent its Member State at the Management Board of the AI Office. (AM 745)*** 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~~. ***Each national supervisory authority should act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation. (AM 745)***

(77a) 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 therelevant national competent authorities, the Commission and with the AI Office. (AM 746)

(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' ***or evolve*** 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 (AM 748)*** resulting from the use of their AI systems ***and take appropriate corrective actions***. ***Deployers should also report to the relevant authorities, any serious incidents or breaches to national and Union law resulting from the use of their AI system when they become aware of such serious incidents or breaches. (AM 39)***

(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. ***For the purpose of this Regulation, national supervisory authorities should act as market surveillance authorities for AI systems covered by this Regulation except for AI systems covered by Annex II of this Regulation. For AI systems covered by legal acts listed in the Annex II, the competent authorites under those legal acts should remain the lead authority. National supervisory authorities and competent authorities in the legislation listed***

Obtenu par CONTEXTE

in Annex II should work together whenever necessary. When appropriate, the competent authorities in the legislation listed in Annex II should send competent staff to the national supervisory authority in order to assist in the performance of its tasks. For the purpose of this Regulation, national supervisory authorities should have the same powers and obligations as market surveillance authorities under Regulation (EU) 2019/1020. 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.

(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 ***competent (AM 755)*** 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[22], 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~~ ***deployers*** of high-risk AI systems to the extent that these apply to credit institutions regulated by Directive 2013/36/EU.

(80a) Given the objectives of this Regulation, namely to ensure an equivalent level of protection of health, safety and fundamental rights of natural persons, to ensure the protection of the rule of law and democracy, and to ensure the free movement of AI systems throughout the Union, and taking into account that the mitigation of the risks of AI system against such rights may not be sufficiently achieved at national level or may be subject to diverging interpretation which could ultimately lead to an uneven level of protection of natural persons and create market fragmentation, the national supervisory authorities should be empowered to conduct joint investigations or rely on the union safeguard procedure provided for in this Regulation.. Joint investigations should be initiated where the national supervisory authority have sufficient reasons to believe that an infringement of this Regulation amount to a widespread infringement or a widespread infringement with a Union

22 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).

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dimension, or where the AI system presents a risk which affects or is likely to affect at least 45 million individuals in more than one Member State,. (AM 40)

(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.

(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~~ ***for high-risk AI systems (AM 761)*** 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 Council57 would apply as a safety net.

(84a) As the rights and freedoms of natural and legal persons and groups of natural or legal persons can be seriously undermined by AI systems, it is essential that affected individuals have meaningful access to reporting and redress mechanisms and to be entitled to access proportionate and effective remedies. They should be able to report infringments of this Regulation to their national supervisory authority and have the right to lodge a complaint against the providers or deployers of AI systems and receive compensation against any direct damage or loss they have with regard to their health, safety, or fundamental rights, due to an infringement of this Regulation by the provider or the deployer. Where applicable, deployers should provide internal complaints mechanisms to be used by affected individuals. Without prejudice to any other administrative or non-judicial remedy, natural and legal persons and groups of natural or legal persons should also have the right to an effective judicial remedy with regard to a legally binding decision of a national supervisory authority concerning them or, where the national supervisory authority does not handle a complaint, does not inform the complainant of the progress or preliminary outcome of the complaint lodged or does not comply with its obligation to reach a final decision, with regard to the complaint. (AMs 46, 751, 767)

(84b) 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. (AM 766)

Obtenu par CONTEXTE

AI ACT - COMPROMISE AMENDEMENTS - BATCH 7 - V4-16.02.2023

AI ACT - COMPROMISE AMENDEMENTS

BATCH 7 - FINAL

TITLE X - Confidentiality and penalties

COMP 10a

Cover: AMs 271, 272, 273, 274, 275, 276 (Rapp), 2795 (EPP), 2796 (RE), 2798 (RE), 2799 (EPP), 2802 (EPP), 2803 (RE), 2806 (S&D), 2807 (ECR), ***2808 (Greens),*** 2809 (S&D), 2810 (EPP), 2811 (EPP)

Fall: ***AMs 2797 (S&D),*** 2800 (EPP), 2801 (Greens), ~~***2804 (EPP), 2805 (ECR***~~) (EPP), JURI 152

~~***Parked: AMs 2797 (S&D), 2808 (Greens)***~~

Article 70
Confidentiality

1. ***The Commission,*** national competent authorities and notified ***bodies,*** ~~***the Commission***~~***, the AI*** ~~***Board***~~ ***Office and any other natural or legal person*** involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular ***(AM 2796)***:
    a. intellectual property rights, and confidential business information or trade secrets of a natural or legal person, ***in accordance*** ~~***line***~~ ***with the provisions of Directive 2004/48/EC and Directive 2016/943/EC*** ~~***and with Directive 2004/48/EC***~~ ***(AM 2799)***, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.
    b. the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;
    c. public and national security interests (***AM 271, 272)***

    ~~***ca. the principles of purpose limitation and data minimisation, meaning that national competent authorities minimize the quantity of data requested for disclosure in line with what is absolutely necessary for the perceived risk and its assessment, and they do not keep the data for any longer than absolutely necessary (AM 2802, 2803, 2807)***~~

    d. integrity of criminal or administrative proceedings.

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1a. The authorities ~~Commission, the Board, national competent authorities and notified bodies~~ involved in the application of this Regulation pursuant to paragraph 1 shall minimise the quantity of data requested for disclosure to the data that is strictly necessary for the perceived risk and the assessment of that risk and shall delete the data as soon as it is no longer needed for the purpose it was requested for ~~not keep the data for longer than necessary~~ (AM 2802, 2803, 2807) and they shall put in place adequate and effective cybersecurity, technical and organisational measures to protect the security and confidentiality of the information and data obtained in carrying out their tasks and activities (AM 273, 2795, 2796, 2806)

2. Without prejudice to paragraph***s 1 and*** 1***a (AM 274, 2809)***, information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the ~~***user***~~ ***deployer (AM 2808)*** when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement, immigration or asylum authorities, when such disclosure would jeopardise public ~~and~~ ***or*** national security ~~interests~~ ***(AM 2808).***
   When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.

3. Paragraphs 1, ***1a (AM 275)*** and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States.

4. The Commission and Member States may exchange, where ***strictly (AM 276)*** necessary ***and in accordance ~~full compliance~~ with relevant ~~the~~ provisions of international and ~~or~~ trade agreements ~~that may apply~~ (AMs 2810, 2811)***, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Obtenu par CONTEXTE

COMP 10b

Cover: AMs 277, 278, 279, 280, 281 (Rapp), 2812 (S&D), 2815 (EPP), 2817 (EPP), 2818 (EPP), 2819 (S&D), 2820 (RE), 2821 (RE), 2824 (S&D), 2825 (S&D), 2826 (EPP), 2828 (S&D), 2829 (S&D), 2830 (RE), 2831 (RE), 2832 (S&D), 2833 (EPP), 2835 (TheLeft), 2836 (S&D), 2837 (EPP), 2838 (RE), 2839 (RE), 2840 (RE), 2841 (EPP), 2842 (RE), 2843 (EPP), 2844 (S&D), 2845 (RE), 2847 (EPP), 2848 (RE), 2852 (EPP), 2853 (RE), 2855 (EPP), 2862 (EPP), 2863 (EPP), 2864 (RE), 2868 (EPP), 2869 (EPP), 2870 (EPP), 2871 (EPP), 2872(EPP), 2874 (EPP), 2876 (RE), 2877 (S&D), 2878 (EPP), 2883 (EPP), CULT 62

Fall: ***AM 2813 (Left),*** 2814 (ID), 2816 (Greens), 2822 (ECR), 2823 (EPP), 2827 (RE), 2834 (ID), 2846 (S&D), 2849 (S&D), 2850 (TheLeft), 2851 (Greens), 2854 (S&D), 2856 (TheLeft), 2857 (Greens), 2858 (S&D), 2859 (EPP), 2860 (Greens), 2861 (S&D), 2865 (S&D), 2866 (RE), 2867 (EPP), 2873 (EPP), 2875 (S&D), 2879 (S&D), ~~***2880 (EPP), 2881 (RE),***~~ 2882 (EPP)

~~***Parked: AM 2813 (Left) - remedies***~~, ~~2819 (S&D)~~

Article 71

Penalties ~~***and fines (AM 277)***~~

1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, ~~***including administrative fines***~~, applicable to infringements of this Regulation ***by any operators***, ~~***in particular for infringements which are not subject to administrative fines pursuant to Article 70a / paragraph 8b (AM2819)***~~ and shall take all measures necessary to ensure that they are properly and effectively implemented ***and aligned with the guidelines issued by the Commission and the*** ~~***Board***~~ ***Office pursuant to,*** ~~***as referred to***~~ ***in Article 58(xxx) (AM 2815, 2818).*** The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into ***particular*** account the ~~***size,***~~ ***the*** interests of ~~***small-scale providers***~~ ***SMEs (AM 2817, 2818, 2820, 2821, 2878)*** and start-up***s*** and their economic viability.

2. ***The*** Member States shall notify the Commission ***and the*** ~~***Board***~~ ***Office (AM 278) by [***~~***3***~~ ***12 months following the date of entry into force of this Regulation] (AM 2824, 2825)*** of those rules and of those measures and shall notify ***them it***~~***,***~~ without delay, of any subsequent amendment affecting them.

3. ***Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** ~~***The following infringements***~~ shall be subject to administrative fines of up to ***40*** ~~***30***~~ 000 000 EUR or, if the offender is ***a*** company, up to ***7*** ~~***6***~~ % of its total worldwide annual turnover for the preceding financial year, whichever is higher:
    a. ~~***non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;***~~
    b. ~~***non-compliance of the AI system with the requirements laid down in Article 10. (AM 2836 to 2844)***~~

3a. Non-compliance of the AI system with the requirements laid down in Article 10 and 13 shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender

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is a company, up to 4% of its total worldwide annual turnover for the preceding financial year, whichever is the higher (AM 2845)

4. ~~***The***~~ Non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5, ~~and~~ 10 ***and 13***, shall be subject to administrative fines of up to ~~***20 000 000***~~ ***10 000 000*** EUR or, if the offender is a company, up to ~~***4%***~~ ***2%*** of its total worldwide annual turnover for the preceding financial year, whichever is higher.***(AM 2847, 2848, 2853).***

5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to ~~***10***~~ ***5*** 000 000 EUR or, if the offender is a company, up to ~~***2***~~ ***1*** % of its total worldwide annual turnover for the preceding financial year, whichever is higher ~~***(AM 2855)***~~.

6. ***Fines may be imposed in addition to or instead of non-monetary measures such as orders or warnings (AM 2862).***When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

    a. the nature, gravity and duration of the infringement and of its consequences, ***taking into account*** ~~***the nature, scope or***~~ ***purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them (AM 2812, 2863)***;

    b. whether administrative fines have been already applied by other ~~*market surveillance*~~ ***national supervisory*** authorities ***of one or more Member States (AM 2864)*** to the same operator for the same infringement.

    c. the size ***and annual turnover*** ~~***and market share***~~ of the operator ***committing the infringement (AM 2847, 2848)***

(ca) any action taken by the operator ~~***provider***~~ ***to mitigate the harm of damage suffered by the affected persons (AM 2868, 2812)***

(cb) the intentional or negligent character of the infringement (AM 2869, 2874, 2812)

(cc) the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement (AM 2870, 2812)

(cca) the degree of responsibility of the operator taking into account the technical and organisational measures implemented by them; (AM 2812)

(ccb) the manner in which the infringement became known to the national competent authorities, in particular whether, and if so to what extent, the operator notified the infringement;

(ccc)adherence to approved codes of conduct or approved certification mechanisms; (AM 2812)

Obtenu par CONTEXTE

(cd) any relevant previous infringements by the operator ~~provider~~ (AM 2871, 2812)

(ce) any other aggravating or mitigating factor applicable to the circumstances of the case (AM 2872, 2812)

7. Each Member State shall lay down rules on ***~~whether and to what extent~~*** administrative fines ***to ~~may~~*** be imposed on public authorities and bodies established in that Member State ***~~with a view to ensure compliance with this Regulation (AM 2876)~~***

8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.

8a. The penalties referred to in this article as well as the associated litigation costs and indemnification claims may not be the subject of contractual clauses or other form of burden-sharing agreements between providers and distributors, importers, ~~users~~ deployers, or any other third parties (AM 2882).

8c. ~~The Commission and~~ National supervisory authorities shall, on an annual basis, report to the ~~Board~~ AI Office about the fines they have issued during that year, in accordance with this Article (AM 281)

8d. The exercise by competent authorities of their powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including judicial remedy and due process (AMs 2812, 2883)

Obtenu par CONTEXTE

COMP 10c

Cover: AMs 282, 283 (Rapp), 2885 (S&D), 2886 (S&D), , 2888 (ECR), 2890 (ECR), 2891 (ECR), 2892 (S&D), 2894 (S&D), 2895 (RE), 2896 (S&D), 2899 (S&D), 2900 (S&D), 2901 (RE), 2902 (S&D), 2903 (S&D), 2904 (RE), 2905 (S&D), 2906 (RE) , 2909 (S&D), 2910 (RE), 2911 (S&D), 2912 (S&D), 2913 (S&D), 2915 (S&D), 2916 (S&D), TRAN 123, 124, 125,

Fall: AMs 2884 (TheLeft), 2887 (ECR), 2889 (ID), 2893 (ECR) 2897 (ID), 2898 (TheLeft), 2907 (ID), 2908 (TheLeft), 2912 (S&D), 2913 (S&D), 2914 (ID), TRAN 126

Article 72
Administrative fines on Union institutions, agencies and bodies

1. The European Data Protection Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

    a) the nature, gravity and duration of the infringement and of its consequences;, ***taking into account ~~the nature, scope or~~ purpose of the AI system concerned as well as the number of affected persons and the level of damage suffered by them, and any relevant previous infringement (AMs 2885, TRAN 123);***

    (aa) any action taken by the Union institution, agency or body to mitigate the damage suffered by affected persons ~~or harm~~ (AM 2886, 2891, TRAN 125)

    (ab) the degree of responsibility of the Union institution, agency or body, taking into account technical and organisational measures implemented by them ;

    (b) the ***degree of*** cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter (***TRAN 124, AM 2890)***

    (c) any similar previous infringements by the Union institution, agency or body ***(AM 2888)***

    (d) the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if

Obtenu par CONTEXTE

so to what extent, the Union institution or body notified the infringement (AM 2892);

(e) the annual budget of the body

2. ***Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5*** ~~***The following infringements***~~ shall be subject to administrative fines of up to ***1 500 000*** ~~***500 000***~~ EUR**.**

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

2a. Non-compliance of the AI system with the requirements laid down in Article 10 ***shall be subject to administrative fines of up to 1 000 000 EUR (AM 2894, 2895, 2896, 2899, 2900, 2901, 2902, 2903, 2904, 2905, 2906)***

3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to ***750 000*** ~~***250 000***~~ EUR (***AM 2909, 2910, 2911)***.

4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.

5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.

6. Funds collected by imposition of fines in this Article shall ***contribute to*** ~~***be the income of***~~ ***(AM 282, 2915)*** the general budget of the Union. ***The fines shall not affect the functioning of the EU bodies fined.***

6a. The European Data Protection Supervisor shall, on an annual basis, notify the ~~***Board***~~ ***AI Office of the fines it has imposed pursuant to this Article (AM 283, 2916)***

Obtenu par CONTEXTE

TITLE XI - delegation of power and committee procedure

COMP 11a

Cover: AMs 2920 (EPP), 2924 (Greens), 2926 (RE), 2927 (Greens), 2929 (TheLeft), CULT 63

Fall:

Article 73
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. ***The power to adopt delegated acts referred to in*** ~~***The delegation of power referred to in***~~ Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for ***a period of five years*** ~~an indeterminate period of time~~ from [***the date of entry*** ~~***entering***~~ into force of the Regulation].***The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

3a. Before adopting a delegated act, the Commission shall ~~***undergo due process and***~~ ***consult with the relevant institutions, the Office, the Advisory Forum and other relevant stakeholders in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making,*** ~~***as well as with the Board/Office and the high level expert Group on AI***~~ ***(CULT 63, AM 2920, 2924)***

~~***3b. Delegated acts that lead to the modification or the addition of obligations on operators shall specify a proportionate transition period when deemed necessary. This transition period shall no less than 24 months (AM 2926)***~~

Once the Commission decides to draft a delegated act, it shall notify the European Parliament of this fact. This notification does not place an obligation on the Commission to adopt the said act (AM 2927, 2929).

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament ~~***and to***~~ ***and to*** the Council ~~***and the AI office***~~ ***(AM 2928)***.

Objet : Par CONTEXTE

5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Obtenu par CONTEXTE

Article 74
Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Obtenu par CONTEXTE

TITLE XII

FINAL PROVISIONS

COMP AM 12a

Covers: 284 (Rapp), 285 (Rapp), 286 (Rapp), 2933 (ECR), 2934 (EPP), 2935 (EPP), 1936 (EPP), 2938 (EPP), 2939 (ECR), 2940 (ECR), 2841 (EPP), 2942 (RE), 2945 (RE), 2946 (RE), 2947 (The Left), 2948 (Greens), 2952 (RE), 2953 (S&D, 2954 (Greens), 2957 (RE), 2959 (Greens), 2960 (S&D), 2962 (RE), 2964 (The Left), 2965 (S&D), 2966 (ECR), 2968 (RE), ***2971 (RE),*** 2975 (RE), 2977 (RE), 2978 (EPP), 2979 (EPP), 2980 (Greens), 2981 (RE), 2982 (RE), 2983 (RE), 2984 (The Left), 2985 (S&D), 2986 (Greens, RE, EPP), 2987 (Greens), 2988 (RE), 2989 (RE), 2990 (S&D), 2991 (The Left), 2992 (Greens), 2993 (Greens, RE, EPP), 2994 (RE), 2995 (Greens), 2996 (The Left), 2997 (S&D), 2998 (EPP), JURI 153

Falls: 2943 (S&D), 2944 (ID), 2949 (EPP), 2950 (RE), 2951 (The Left), 3000 (EPP), 3001 (RE), 3002 (EPP) 3003 (Greens), 3004 (EPP), 3005 (EPP), 3006 (EPP), 3007 (RE), 2955 (EPP), 2958 (ID), 2961 (RE), 2962 (RE), ***2967 (EPP***), 2973 (ECR), ***2975 (S&D)***

~~***Parked: 2963 (Greens) - AI in employment, 2967 (EPP) - linked to debate on Article 7, 2975 (S&D), 2971 (RE) - governance and fines***~~

Article 75
Amendment to Regulation (EC) No 300/2008

In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:

"When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account."

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* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)."

Article 76
Amendment to Regulation (EU) No 167/2013

In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:

"When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

_____

Obtenu par CONFIDENTIEL

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”

Article 77
Amendment to Regulation (EU) No 168/2013

In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:

“When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

_____

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”

Article 78
Amendment to Directive 2014/90/EU

In Article 8 of Directive 2014/90/EU, the following paragraph is added:

“4. For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.

_____

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”.

Article 79
Amendment to Directive (EU) 2016/797

In Article 5 of Directive (EU) 2016/797, the following paragraph is added:

“12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

_____

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).”.

Article 80
Amendment to Regulation (EU) 2018/858

In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:

Obtenu par CONTEXTE

"4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council *, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

_____

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).".

Article 81
Amendment to Regulation (EU) 2018/1139

Regulation (EU) 2018/1139 is amended as follows:

(1) In Article 17, the following paragraph is added:

"3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [*on Artificial Intelligence*] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

Article 81a

Amendment to Regulation (EU) 2019/1020

Regulation (EU) 2019/1020 is amended as follows:

In Article 14(4) ~~of Regulation (EU) 2019/1020,~~ the following paragraph is added:

"(l) The power to implement the powers provided for in this Article remotely, where applicable." (AM 2937)

_____

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …)."

(2) In Article 19, the following paragraph is added:

"4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."

(3) In Article 43, the following paragraph is added:

"4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."

(4) In Article 47, the following paragraph is added:

"3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/

Obtenu par CONTEXTE

XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."

(5) In Article 57, the following paragraph is added:

"When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."

(6) In Article 58, the following paragraph is added:

"3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence] , the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.".

Article 82
Amendment to Regulation (EU) 2019/2144

In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:

"3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence] of the European Parliament and of the Council*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

_____

* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ …).".

Article 82 a
Better~~Sound~~ regulation

In taking into account the requirements of this Regulation pursuant to the Amendments in Articles 75, 76, 77, 78, 79, 80, 81, and 82, the Commission shall conduct an analysis and consult relevant stakeholders to determine potential gaps as well as overlaps between existing sectoral legislation and the provisions of this Regulation ~~in order to avoid duplication, overregulation, and the creation of loopholes.~~ (AMs 2942, 2933, 2934, 2935, 1936, 2938, 2939, 2940, 2941)

Article 83
AI systems already placed on the market or put into service

1. ***Operators of (AM 2946)***the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service ***prior to ... [the date of entry into force of this Regulation] shall take the necessary steps to comply with the requirements ~~of the present~~ laid down in this Regulation ~~within~~ by [4 years after the date of entry into***

Obtenu par CONTEXTE

force of this Regulation] ~~4 years after the entry into force of this Regulation~~ (AM 2945, 2946, 2947, 2948)

The requirements laid down in this Regulation shall ***be taken into account (AMs 2953, 2954)*** in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts ***and whenever those legal acts are replaced or amended (AM 2952)***.

2. This Regulation shall apply to ***operators of*** high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [*date of application of this Regulation referred to in Article 85(2)*], ***only if, from that date, those systems are subject to substantial modifications as defined in Article 3(23***). ***In the case of high-risk AI systems intended to be used by public authorities, providers and ~~users~~ deployers of such systems shall take the necessary steps to comply with the requirements of the present Regulation within 2 years of its entry into force (AMs 2957, ~~2959,~~ 2960, 2962)***

Article 84
Evaluation and review

1. ***After consulting ~~In consultation with~~ the AI ~~Board~~ Office,*** the Commission ***(AM 2970)*** shall assess the need for amendment of the list in Annex III***, including the extension of existing area headings or addition of new area headings in that Annex; the list of prohibited AI practices in Article 5 ~~'s list of prohibited AI practices~~, and ~~Article 52's~~ the list of AI systems requiring additional transparency measures in Article 52 (AMs 2964, 2965, 2969)*** once a year following the entry into force of this Regulation ***and ~~on a regular basis~~ following a recommendation of the ~~Board~~ AI Office (AM 284, 2971)***. ***The Commission shall submit the findings of that assessment ~~shall be presented~~ to the European Parliament and the Council. (AMs 2966, 2968, 2972)***

2. By [**two** *years after the date of application of this Regulation referred to in Article 85(2)*] and every ***two (AM 285)*** years thereafter, the Commission, ***together with the AI office,*** shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

3. The reports referred to in paragraph 2 shall devote specific attention to the following:

   (a) the status of the financial***, technical (AM 2974)*** and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

   (b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation

Obtained for CONTEXTE

(ba) the level ~~state~~ of the development of harmonised standards and common specifications for Artificial Intelligence; (AM 2977)

(bb) the levels of investments in research, development and application of AI systems throughout the Union; (AM 2978)

(bc) the competitiveness of the aggregated European AI ~~ecosystem~~ sector compared to AI sectors ~~ecosystems~~ in third countries (AM 2979)

bca) ~~the impact of the Regulation on fundamental rights;~~

(bd) the impact of the Regulation with regards to the resource and energy use, as well as waste production and other environmental impact (AM 2980)

(be) the implementation of the Coordinated Plan on AI, taking into account the different level of progress among Member States and identifying existing barriers to innovation in AI.

3a. By [2 year after the date of entry into application of this Regulation referred to in Article 85(2)] the Commission shall evaluate the functioning of the AI office, whether the office has been given sufficient powers and competences to fulfil its tasks and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the Office and its enforcement competences and to increase its resources. The Commission shall submit this evaluation report to the European Parliament and to the Council.

4. Within [***one*** *year after the date of application of this Regulation referred to in Article 85(2)*] and every ***two (AM 2981)*** years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.

5. For the purpose of paragraphs 1 to 4 the ***AI ~~Board~~ Office (AM 2983)***, the Member States and national competent authorities shall provide the Commission with information on its request ***without undue delay (AM 2982)***.

6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of ***the AI Office (AM 2989)***, of the European Parliament, of the Council, ***~~of equality bodies (AMs 286, 2984, 2985)~~*** and of other relevant bodies or sources ***and shall consult relevant ~~external~~ stakeholders, ~~in particular those potentially affected by the AI systems, organisations representing their interests, academia, the social partners and civil society~~. The result of such consultation ~~which~~ shall be attached to the report. (AMs 286, 2984, 2985, 2986, 2987, 2988)***

7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology ***the effect of AI systems on health and safety, fundamental rights, the environment, ~~equality, and accessibility for persons with disabilities, and the values of the Union as enshrined in Article 2 TEU~~ democracy and rule of law (AM 2990, 2991, 2992, 2993, 2994,)*** and in the light of the state of progress in the information society.

Obtenu par CONTEXTE

7 a. To guide the evaluations and reviews referred to in paragraphs 1 to 4 of this Article, the ~~Board~~ Office shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the relevant articles and inclusion of new systems in: the list in Annex III, including the extension of existing area headings or addition of new area headings in that Annex; the list of prohibited practices laid down in Article 5; and the list of AI systems requiring additional transparency measures pursuant to Article 52. (AMs 2996, 2997)

7b. Any amendment to this Regulation pursuant to paragraph 7 of this Article, or relevant future delegated or implementing acts, which concern sectoral legislation listed in Annex II Section B, shall take into account the regulatory specificities of each sector, and ~~should not interfere with~~ existing governance, conformity assessment and enforcement mechanisms and authorities established therein. (AM 2998)

7c. By ~~three~~ five years from the date of application of this Regulation at the latest, the Commission shall carry out an assessment of the enforcement of this Regulation and shall report it to the European Parliament, the Council and the European Economic and Social Committee, taking into account the first years of application of the Regulation. On the basis of the findings that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for an EU agency to resolve any identified shortcomings. (AM 2995, JURI 153)

Article XX

Guidelines from the Commission on the implementation of this Regulation

1. The Commission shall develop, in consultation with the AI office, guidelines on the practical implementation of this Regulation, and in particular on:

(i) the application of the requirements referred to in Articles 8 - 15 and Article 28 to 28b

(ii) the prohibited practices referred to in Article 5;

(iii) the practical implementation of the provisions related to substantial modification;

(iv) the practical circumstances where the output of an AI system referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons as referred to in Article 6, paragraph 2, including examples in relation to high risk AI systems referred to in Annex III;

(v) the practical implementation of transparency obligations laid down in Article 52;

(vi) the development of codes of conduct referred to in Article 69

(vii) the relationship of this Regulation with other relevant Union legislation, including as regards consistency in their enforcement.

Obtenu par CONTEXTE

(viii) the practical implementation of XX on environmental impact of high-risk AI systems

When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, local public authorities and sectors most likely to be affected by this Regulation.

2. Upon request of the Member States or the AI Office, or on its own initiative, the Commission shall update already adopted guidelines when deemed necessary.

Article 85
Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. This Regulation shall apply from [24 months following the entering into force of the Regulation].
3. By way of derogation from paragraph 2:
   (a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];
   (b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Matching recitals:

COMP 12b

Covers: AM 44 (Rapp), 2804 (EPP), 2805 (ECR), 763 (EPP), 764 (S&D), 771 (Greens), 772 (S&D), 773 (RE), 774 (Greens), 777 (Greens), 778 (Greens), JURI 20, JURI 21, CULT 23, CULT 24
Falls: AM 45 (Rapp), 762 (Greens), 769 (ID), 770 (EPP), 775 (EPP), 776 (Greens), ***CULT 22***

(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 while*** respect***ing (AM 762)*** the confidentiality of information and data obtained in carrying out their tasks ***by putting in place technical and organisational measures to protect the security and confidentiality of the information obtained carrying out their activities including for intellectual property rights and public and national security interests. In cases where the activities of the Commission, national competent authorities and notified bodies pursuant to this Regulation results in a breach of intellectual property rights, Member States should provide for adequate measures and***

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remedies to ensure the enforcement of intellectual property rights in application of Directive 2004/48/EC (2804, 2805). ~~***The relevant competent authorities should put in place adequate cybersecurity and organisational measures to protect the security and confidentiality of the information and data obtained in carrying out their tasks and activities (AM 44).***~~

(84) ***Compliance with this Regulation should be enforceable by means of the imposition of fines by the national supervisory authority when carrying out proceedings under the procedure laid down in this Regulation. (AM 45)*** 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. ***In order to strengthen and harmonise administrative penalties for infringement of this Regulation, this Regulation set up the upper limits for setting the administrative fines (764).*** ~~For~~ ***for*** certain specific infringements, ~~***Member States should take into account the margins and criteria set out in this Regulation***~~. ***When assessing the amount of the fines, national competent authorities should, in each individual case, take 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 (764) and to the provider's size, in particular if the provider is a SME or a start-up.*** 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 (AM 763)***

(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, civil society, associations representing affected persons, businesses representatives from different sectors and sizes, as well as researchers and scientists (AM 771, 773, JURI 20, CULT 23).*** 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.

(85a) Given the rapid technological developments and the required technical expertise in conducting the assessment of high-risk AI systems, the Commission should regularly review Article 5, Articles 52 and Annex III, at least every year, while consulting the AI office and the relevant stakeholders (AMs 774, JURI 21, CULT 24)

(86) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

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(87) Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(87a) As reliable information on the resource and energy use, waste production and other environmental impact of AI systems and related ICT technology, including software, hardware and in particular data centres, is limited, the Commission should evaluate the introduction of an adequate methodology to measure the environmental impact and effectiveness of this Regulation in light of the Union environmental and climate objectives (777)

(88) This Regulation should apply from … [*OP – please insert the date established in Art. 85*]. However, the infrastructure related to the governance and the conformity assessment system should be operational before that date, therefore the provisions on notified bodies and governance structure should apply from … [*OP – please insert the date – three months following the entry into force of this Regulation*]. In addition, Member States should lay down and notify to the Commission the rules on penalties, including administrative fines, and ensure that they are properly and effectively implemented by the date of application of this Regulation. Therefore the provisions on penalties should apply from [*OP – please insert the date – twelve months following the entry into force of this Regulation*].

(89) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(2) of Regulation (EU) 2018/1725 and delivered an opinion on ***18.6.2021 (778)***

COMPROMISE AMENDMENT XX - Annex II & III - Version 3 - 04/03/2023 (V3FINAL without recitals (002))

CA XX

Covers:

Falls: 3035 (Greens); 3040 (Greens 3031 (EPP); 3032 (EPP); 3033 (EPP); 3034 (EPP); 3036 (ID); 3037 (ID); 3038 (EPP); 3039 (EPP); 3041 (EPP);

ANNEX II
LIST OF UNION HARMONISATION LEGISLATION
Section A – List of Union harmonisation legislation based on the New Legislative Framework

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];
2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);

Obtenu par CONTEXTE

3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Section B. List of other Union harmonisation legislation

13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

Obtenu par CONTEXTE

15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);

16. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);

17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1); 3. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);

19. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.

Obtenu par CONTEXTE

CA XX

Covers: **290 (Rapp); 291 (Rapp); 292 (Rapp); 3046 (EPP); 3047 (RE), 3048 (EPP); 3049 (ECR), 3050 (Greens), 3051 (ECR), 3052 (The Left), 3053 (S&D), 3059 (RE); 3066 (RE), 3067 (S&D); 3068 (The Left); 3069 (Greens); 3071 (The Left); 3072 (ECR); 3073 (The left); 3074 (Greens); 3075 (S&D); 3076 (The Left); 3077 (The Left); 3078 (The left); 3079 (Greens); 3080 (S&D); 3081 (The left); 3082 (The Left); 3083 (Greens); 3084 (The Left); 3085 (Greens); 3086 (The Left); 3094 (EPP), 3095 (EPP), 3096 (S&D), 3097 (EPP), 3099 (S&D), 3101 (EPP), 3102 (RE), 3104 (TheLeft), 3113 (ECR), 3114 (Greens); 3115 (S&D); 3116 (The Left); 3117 (RE); 3118 (RE), 3122 (The Left); 3125 (RE); 3130 (ECR); 3132 (The Left); 3135 (S&D); 3137 (S&D); 3140 (S&D); 3143 (Greens); 3144 (ECR); 3145 (EPP); 3146 (Greens); 3147 (Greens); 3149 (S&D), 3150 (Greens), 3151 (TheLeft), 3152 (TheLeft), 3163 (RE), 3164 (RE), 3166 (RE), 3168 (RE), 3169 (RE), 3170 (S&D), 3172 (RE), 3174 (TheLeft), 3175 (TheLeft), 3176 (Greens), 3177 (RE), 3178 (S&D), 3182 (RE), 3184 (RE), 3188 (RE), 3195 (RE); 3196 (RE); 3201 (Greens); 3202 (The Left); 3203 (RE-EPP-Greens); 3204 (RE); 3205 (RE); 3207 (RE); 3208 (RE); 3211 (RE - EPP-Greens); 3212 (The Left); 3213 (RE); 3214 (RE); 3216 (RE); 3217 (Greens); 3218 (RE); 3219 (The Left); 3220 (RE-EPP-Greens); 3221 (The Left); 3223 (The Left); 3224 (RE); 3225 (The Left); 3226 (RE-EPP-Greens); 3227 (The left); 3230 (RE), 3231 (Greens), 3232 (EPP), 3233 (RE), 3225 (RE), 3236 (Greens), 3237 (RE), 3238 (S&D), CULT 71; ENVI 105; ENVI 106,**

Falls: **3042 (S&D), 3043 (EPP), 3044 (EPP), 3045 (RE), 3054 (EPP); 3055 (EPP); 3056 (RE); 3057 (Greens); 3058 (S&D); 3060 (S&D); 3061 (ID): 3062 (EPP); 3063 (ECR); 3064 (The Left); 3065 (ECR); 3070 (ID); 3087 (TheLeft) 3088 (EPP), 3089 (The Left), 3090 (ECR), 3091 (Greens), 3092 (EPP), 3093 (EPP), 3098 (Greens), 3100 (Greens), 3103 (Greens), 3105 (EPP); 3106 (EPP); 3107 (EPP); 3108 (RE); 3109 (Greens); 3110 (RE); 3111 (EPP); 3112 (EPP); 3119 (EPP); 3120 (S&D); 3121 (RE); 3123 (Greens); 3124 (EPP); 3126 (EPP); 3127 (The Left); 3128 (EPP); 3129 (S&D); 3131 (ECR); 3133 (Greens); 3134 (Greens); 3136 (RE); 3138 (S&D); 3139 (S&D); 3141 (ID); 3142 (Greens); 3148 (ID), 3153 (EPP), 3154 (RE), 3155 (EPP), 3156 (ID), 3157 (S&D), 3158 (RE), 3159 (TheLeft), 3160 (TheLeft), 3161 (TheLeft) 3162 (Greens), 3165 (S&D), 3167 (Greens), 3171 (Greens) 3173 (ID), 3179 (EPP), 3180 (ID), 3181 (TheLeft), 3183 (Greens), 3185 (TheLeft), 3186 (EPP), 3187 (Greens), 3189 (Greens); 3190 (RE); 3191 (The Left); 3192 (The Left); 3193 (S&D); 3194 (S&D); 3197 (S&D); 3198 (The lEft); 3199 (RE); 3200 (S&D); 3206 (Greens); 3209 (S&D); 3210 (S&D); 3215 (Greens); 3228 (ID), 3229 (EPP), ~~3231 (Greens),~~ 3234 (RE), 3239 (TheLeft), 3240 (Greens), 3241 (misc)**

Parked:3079 (Greens); 3082 (The Left); 3083 (Greens);

ANNEX III
HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

The AI systems specifically mentioned under points 1-8a stand for critical use cases and are each considered to be high-risk AI systems pursuant to Article 6(2) ~~***are the AI systems listed in any of the following areas***~~***, provided that they fulfil the criteria set out in that Article (AM 3046)***:

OBSERVATOIRE CONFIDENTIEL

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

1. Biometric and biometrics-based systems:

(a) AI systems intended to be used for ~~post~~ ~~remote~~ biometric identification of natural persons, with the exception of those mentioned in Article 5 (AMs 3067; 3068; 3069; 3071; 3073; 3074; 3076; 3077; 3079; 3083; 3084);

(b) ~~AI systems intended to be used for the remote biometric categorisation of natural persons in publicly accessible spaces;~~(b) AI systems intended to be used to make inferences about personal characteristics of natural persons on the basis of biometric or biometrics-based data, including emotion recognition systems, with the exception of those mentioned in Article 5 (AM 3066); (AMs 3047, 3049, 3050, 3051, 3052, 3053, 3066, 3072; 3073; 3082)

(d) ~~AI systems that are intended to be used for real-time and post biometric identification of natural persons in privately accessible spaces; (AMs 3067; 3068; 3069; 3071; 3073; 3074; 3076; 3077; 3079; 3083; 3084)~~

Point 1 shall not include AI systems intended to be used for biometric verification whose sole purpose is to confirm that a specific natural person is the person he or she claims to be., (AMs 3048 3059).

2. Management and operation of critical infrastructure:

(a) AI systems intended to be used as safety components in the management and operation of road, ***rail and air*** traffic ***unless these are regulated in harmonisation or sectoral legislation.(AM 3092)***

(ba) ***AI systems intended to be used as safety components in the management and operation of ~~and~~*** the supply of water, gas, heating, ***~~energy~~ and*** electricity ***and critical digital infrastructure ~~provided the failure of the AI system is highly likely to lead to an imminent threat to such supply~~ (AM 3089, 3094, 3095);***

3. Education and vocational training:

(a) AI systems intended to be used for the purpose of determining access ***or materially influence decisions on admission*** or assigning natural persons to educational and vocational training institutions; (***AM 3097)***

(b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to ***those ~~educational~~*** institutions***, ~~or for deciding or allocating personalised learning tasks to students based on students' personal data~~ (AM 3099, 3101, 3102, 3104)***

(c) ***AI systems ~~that may be or are~~ intended to be used for the purpose of assessing the appropriate level of education for an individual and ~~with the potential effects for the method or~~ materially influencing the level of education and vocational training that individual will receive or will be able to access. (AM 3103; CULT 68)***

Obtenu par CONSYLEX

(d) AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests in the context of/within education and vocational training institutions; (AM CULT 69)

4. Employment, workers management and access to self-employment:

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

(b) AI ***systems*** intended to be used ~~for making~~ ***to make or materially influence*** decisions ~~***or assisting in making decisions***~~ ***affecting the initiation,*** ~~***establishment, implementation***~~***,*** ~~on~~ promotion and termination of ~~***an employment relationship particularly***~~ work-related contractual relationships, ***task allocation based on individual behaviour or personal traits or characteristics,*** ~~for ***personalized*** task allocation ***based on biometrics, biometrics-based, or personal data, or for monitoring compliance with workplace rules*** and~~ ***or*** for monitoring and evaluating performance and behavior of persons ~~***or determining access to training or further education***~~ in such relationships. ***(AMs 3113; 3114, 3115, 3116, 3117, 3118; CULT 71)***

5. Access to and enjoyment of essential private services and public services and benefits:

(a) AI systems intended to be used by ***or on behalf of*** public authorities ~~or on behalf of public authorities~~ to evaluate the eligibility of natural persons for public assistance benefits and services, ***including healthcare services, and essential services, including but not limited to housing, electricity, heating/ cooling and internet,*** as well as to grant, reduce, revoke, ***increase*** or reclaim such benefits and services; ***(AMs 3122; 3125; ENVI 105)***

(b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score***, with the exception of AI systems used for the purpose of detecting financial fraud*** ~~the exception of AI systems put into service by small scale providers for their own use~~; ***(AMs 290; 3132; 3135; 3137)***

(bb) AI systems intended to be used for making decisions or ~~***assisting in making***~~ ***or materially influencing decisions on the eligibility of natural persons for health and life insurance; (AMs 291; 3130; 3143; 3144; 3145)***

(c) AI systems intended ***to evaluate and classify emergency calls by natural persons or*** to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including ***by police and law enforcement,*** firefighters and medical aid***, as well as of emergency healthcare patient triage systems***. ***(AMs 292);***

~~***5 a. Use by vulnerable groups or in situations that imply vulnerability:***~~

~~***(a) AI systems intended to be used by children in a way that may seriously affect a child's personal development (AMs 3140; 3096, 3147)***~~

Obtenu par COMITE

6. Law enforcement:

(a) ~~***AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;*** *(3148, 3149, 3150, 3151, 3152)*~~

(b) AI systems intended to be used by ***or on behalf of*** law enforcement authorities***, or by Union agencies, offices or bodies in support of law enforcement authorities*** ~~***or on their behalf***~~ as polygraphs and similar tools; ***insofar as their use is permitted under relevant Union and national law (3163, 3164)***

(c) ~~AI systems intended to be used by law enforcement authorities ***or on their behalf*** to detect deep fakes as referred to in article 52(3); ***(3166, 3168)***~~

(d) AI systems intended to be used by ***or on behalf of*** law enforcement authorities***, or by Union agencies, offices or bodies in support of law enforcement authorities*** ~~***or on their behalf***~~ ***to evaluate*** the reliability of evidence in the course of investigation or prosecution of criminal offences; ***(3169, 3170, 3172)***

(e) ~~***AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;*** *(3173, 3174, 3175, 3176, 3177, 3178)*~~

(f) AI systems intended to be used by ***or on behalf of*** law enforcement authorities ~~***or on their behalf***~~ ***or by Union agencies, offices or bodies in support of law enforcement authorities*** for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences ***or, in the case of Union agencies, offices or bodies, as referred to in Article 3(5) of Regulation (EU) 2018/1725***; ***(3182, 3184)***

(g) AI systems intended to be used ***by or on behalf of law enforcement authorities*** ~~***or on their behalf***~~ ***or by Union agencies, offices or bodies in support of law enforcement authorities*** for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data. ***(3188)***

7. Migration, asylum and border control management:

(a) AI systems intended to be used by ***or on behalf of*** competent public authorities ***or by Union agencies, offices or bodies*** as polygraphs and similar tools, ***insofar as their use is permitted under relevant Union or national law;***; ***(AMs 3195, 3196)***

Obtenu par consilium.europa.eu

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

(c) AI systems intended to be used by ***or on behalf of*** competent public authorities ***(AM 3201, 3202; 3203; 3204; 3205; 3207; 3208) or by Union agencies, offices or bodies*** ~~***in support of law enforcement authorities***~~ for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;

(d) AI systems intended to ***be used by or on behalf of competent public authorities (AMs 3213; 3214; 3216) or by Union agencies, offices or bodies*** ~~***in support of law enforcement authorities***~~ ***to*** assist competent public authorities for the examination ***and assessment of the veracity of evidence in relation to (AMs 3211; 3212)*** ~~of~~ applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

(e) AI systems intended to be used by or on behalf of competent public authorities or by Union agencies, offices or bodies ~~***in support of law enforcement authorities***~~ ***in migration, asylum and border control management, to monitor, surveil or process data in the context of border management activities, for the purpose of detecting, recognising or identifying natural persons (AMs 3217, 3223, 3226, 3227)***

(f) ***AI systems intended to be used by or on behalf of competent public authorities or by Union agencies, offices or bodies*** ~~***in support of law enforcement authorities***~~ ***in migration, asylum and border control management for the forecasting or prediction of trends related to migration movement and border crossing (AMs 3218, 3219, 3220)***

8. Administration of justice and democratic processes:

(a) AI systems intended ***to be used by a judicial authority ot administrative body or on their behalf*** to assist a judicial authority ***or administrative body*** in researching and interpreting facts and the law and in applying the law to a concrete set of facts ***or used in a similar way in alternative dispute resolution. (3230, 3232, 3231, 3233)***

ab) AI systems intended to be used ~~***by political parties, political candidates, public authorities, or on their behalf***~~ ***for influencing the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda*** ~~***in local, national, or European elections***~~ ***(3235)***

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This does not include AI systems whose output natural persons are not directly exposed to, such as tools used to organise, optimise and structure political campaigns from an administrative and logistic point of view.

(ad) AI systems intended to be used by social media platforms that have been designated as very large online platforms within the meaning of Article 33 of Regulation EU2022/2065, in their recommender systems to recommend to the recipient of the service user-generated content available on the platform..

Recital

Considering the scale of natural persons using the services provided by social media platforms designated as very large online platforms, such online platforms can be used in a way that strongly influences safety online, the shaping of public opinion and discourse, election and democratic processes and societal concerns. It is therefore appropriate that AI systems used by those online platforms in their recommender systems are subject to this Regulation so as to ensure that the AI systems comply with the requirements laid down under this Regulation, including the technical requirements on data governance, technical documentation and traceability, transparency, human oversight, accuracy and robustness. Compliance with this Regulation should enable such very large online platforms to comply with their broader risk assessment and risk-mitigation obligations in Article 34 and 35 of Regulation EU 2022/2065. The obligations in this Regulation are without prejudice to Regulation (EU) 2022/2065 and should complement the obligations required under the Regulation (EU) 2022/2065 when the social media platform has been designated as a very large online platform.

Changes compared the previous version are
Changes from last TM are marked with a comments 'TM 24/04"

Compromise proposal on General purpose AI systems/value chain

Recital 49

(49) High-risk AI systems should perform consistently throughout their lifecycle and meet an appropriate level of performance, robustness and cybersecurity in accordance with the generally acknowledged state of the art. ***Performance metrics and their expected level should be defined with the primary objective to mitigate risks and negative impact of the AI system. The expected*** level of ***performance*** metrics should be communicated ***in a clear,***

Obtenu par CONTEXTE

transparent, easily understandable and intelligible way to the deployers. ***The declaration of performance metrics cannot be considered proof of future levels but relevant methods need to be applied to ensure consistant levels during use. While standardisation organisations exist to establish standards, coordination on benchmarking is needed to establish how these standardised requirements and characteristics of AI systems should be measured. The European Artificial Intelligence Office should bring together national and international metrology and benchmarking authorities and provide non-binding guidance to address the technical aspects of how to measure the appropriate levels of performance and robustness.***

Recital 60a (new)

(60a) (new) Foundation models are a recent development, in which AI systems are developed from algorithms designed with the intention to optimize for generality and versatility of output. Those systems can be trained on a broad range of data sources to accomplish a wide range of downstream tasks, including some for which they were not specifically developed and trained. Those systems can be unimodal or multimodal, trained through various methods such as supervised learning or reinforced learning. Foundation models are often the basis for various AI systems with specific intended purpose. These systems hold growing importance to many downstream applications, combined with their complexity and unexpected impact, as well as the downstream operator's lack of control over the AI system's development and consequent power imbalance. Therefore, due to their particular nature and in order to ensure a fair sharing of responsibilities along the AI value chain, such systems should be subject to proportionate and more specific requirements and obligations under this Regulation while ensuring a high level of protection of fundamental rights, health and safety. AI systems developed for a limited set of applications that cannot be adapted for a wide range of tasks such as components, modules, or simple multi-purpose AI systems should not be considered foundation models for the purposes of this Regulation.

Recital 60b (new)

(60b) (new) Requirements for foundation models should be broadly applicable (e.g. independent of distribution channels, modality, development methods), to address risks specific to such AI systems and complementary to measures for high-risk AI systems, and which can be coherently implemented taking into account industry state-of-the-art practices. These requirements include risk management, extensive analysis and testing of the general model for unforeseen vulnerabilities, including by competent evaluators.

Obtenu par CONTEXTE

Article 3
Definitions

For the purpose of this Regulation, the following definitions apply:

(1a) (new) 'foundation model' means an AI ~~system~~ model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;

(1a) (new) 'general purpose AI system' means an AI system that can be used in and adapted to a wide range of applications for which it was not intentionally and specifically designed;

(1c) (new) 'large training runs' means the production process of a powerful AI models that require computing resources above a very high threshold.

Article 28
Responsibilities along the AIvalue chain of providers, distributors, importers, deployers or other third party

1. Any distributor, importer, ***deployer*** or other third-party shall be considered a provider ***of a high-risk AI system (AM 2026)*** for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

   (a) they ***put their name or trademarkt on a high-risk AI system already*** placed on the market or put into service ~~a high-risk AI system~~ ~~under their name or trademark~~

   (b) they ***make a substantial modification to*** a high-risk AI system ***that has*** already ***been*** placed on the market or ***has already been*** put into service ***and in a way that it remains a high-risk AI system in accordance with Article 6; (AM 133)***

   (ba) they make a substantial modification to an AI system, including a general purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such manner that the AI system becomes a high risk AI system in accordance with Article 6 (AM 132, 134, 2031, 2032)

2. Where the circumstances referred to in paragraph 1, point (***a***) ***to (ba)*** ~~***or***~~ ***((AM 135)***, occur, the provider that initially placed the ~~high-risk~~ AI system on the market or put it into service shall no longer be considered a provider ***of that specific AI system*** for the purposes of this Regulation. ***This former provider shall, ~~without compromising its own intellectual property rights or trade secrets,~~ provide the new provider with the technical documentation and all other ~~essential~~ relevant and reasonably***

Obtenu par CONTEXTE

expected information capabilities of the AI system, technical access or other assistance based on the generally acknowledged state of the art that are required for the fulfilment of the obligations set out in this Regulation. (AM 2033)

Pragragph 2 shall also apply to providers of foundation models as defined in Article 3(XX) when the foundation model is directly integrated in an high-risk AI system.

The developers of free and open-source AI components shall not be mandated to comply with such obligations towards the provider that has integrated the free and open-source AI component in his or her high-risk AI system.3. The provider of a high risk AI system and the third party that supplies tools, services, components, ~~including foundation models,~~ or processes that are used or integrated in the high risk AI system shall, by written agreement specify the information, capabilities, technical access, and or other assistance, based on the generally acknowledged state of the art, that the third party must provide in order to enable the provider of the high risk AI system to fully comply with the obligations under this Regulation.

The Commission shall develop and recommend non-binding model contractual terms between providers of high-risk AI systems and third parties that supply tools, services, components, ~~including foundation models~~, or processes that are used or integrated in high-risk AI systems in order to assist both parties in drafting and negotiating contracts with balanced contractual rights and obligations, consistent with each party's level of control. When developing non-binding model contractual terms, the Commission shall take into account possible contractual requirements applicable in specific sectors or business cases. The non-binding contractual terms shall be published and be available free of charge in an easily usable electronic format on the AI Office's website.

4. For the purposes of this Article, trade secrets shall be preserved and shall only be disclosed provided that all specific necessary measures pursuant to Directive (EU) 2016/943 are taken in advance to preserve their confidentiality, in particular with respect to third parties. Where necessary, appropriate technical and organizational arrangements can be agreed to protect intellectual property rights or trade secrets.

Article 28(a) (new)
Unfair contractual terms unilaterally imposed on an SME or start-up

1. A contractual term concerning the supply of tools, services, components or processes that are used or integrated in a high risk AI system or the remedies for the breach or the termination of related obligations which has been unilaterally imposed by an enterprise on a SME or startup shall not be binding on the latter enterprise if it is unfair.

1a. A contractual term is not to be considered unfair where it arises from applicable Union law.

Obtenu par CONTEXE

2. A contractual term is unfair if it is of such a nature that it objectively impairs the ability of the party upon whom the term has been unilaterally imposed to protect its legitimate commercial interest in the information ~~data~~ in question or its use grossly deviates from good commercial practice in the supply of tools, services, components or processes that are used or integrated in a high-risk AI system, contrary to good faith and fair dealing or creates a significant imbalance between the rights and the obligations of the parties in the contract. A contractual term is also unfair if it has the effect of shifting penalties referred to in Article 71 or associated litigation costs across parties to the contract, as referred to in Article 71(8) (new).

3. A contractual term is unfair for the purposes of this Article if its object or effect is to:

(a) exclude or limit the liability of the party that unilaterally imposed the term for intentional acts or gross negligence;
(b) exclude the remedies available to the party upon whom the term has been unilaterally imposed in the case of non-performance of contractual obligations or the liability of the party that unilaterally imposed the term in the case of a breach of those obligations;
(c) give the party that unilaterally imposed the term the exclusive right to determine whether the technical documentation, information ~~or data~~ supplied are in conformity with the contract or to interpret any term of the contract.

3a. A contractual term shall be considered to be unilaterally imposed within the meaning

of this Article if it has been supplied by one contracting party and the other contracting party has not been able to influence its content despite an attempt to negotiate it. The contracting party that supplied a contractual term bears the burden of proving that that term has not been unilaterally imposed.

3. Where the unfair contractual term is severable from the remaining terms of the contract, those remaining terms shall remain binding. The party that supplied the contested term may not argue that the term is an unfair term.

4. This Article shall apply to all new contracts entered into force after ... [date of entry into force of this Regulation]. Businesses shall be given three-years following that date to review existing contractual obligations that are subject to this Regulation.

5. Given the rapidity in which innovations occur in the markets, the list of unfair contractual terms within Article 28a shall be reviewed regularly by the Commission and be updated to new business practices if necessary.

Obtenu par CONTEXTE

Article 28b (new)
Obligations of the provider of a foundation model

1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or ~~distributed through~~ provided under free and open source licences, as a service, as well as other distribution channels.

1a. For the purpose of paragraph 1, the provider of a foundation model shall:

(a) demonstrate through appropriate design, testing and analysis that ~~ensure~~ the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development

(aa) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation

(b) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development,

(c) draw up extensive technical documentation and intelligible instructions for use in order to enable the downstream providers to comply with their obligations pursuant to Article 16 and 28.1.

(d) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,

(e) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII paragraph C.

Obtenu par CONTEXTE

When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected notably in benchmarking guidance and capabilities referred to in Article 58a (new).

4. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 1(c) at the disposal of the national competent authorities

5. Providers of foundation models shall in addition comply with art. 28.1(ba) and 2, as well as Article 28a. In the case of foundation models provided as a service such as through API access, the cooperation referred to in Article 28.2 shall extend throughout the time during which that service is provided to or used by the provider of the downstream AI system, in order to enable appropriate risk mitigation, unless the provider of the foundation model transfers the training model as well as extensive and appropriate information on the datasets and the development process of the system or restricts the service, such as the API access, in such a way that the downstream provider is able to fully comply with this Regulation without futher support from the original provider of the foundation model.

5a. Providers of foundation models ~~specifically intended to be~~ used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI"), shall in addition comply with the transparency obligations outlined in Article 52(1), design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression, and document and make publicly available a summary of the use of training data protected under copyright law. Providers of foundation models shall assist the downstream providers of such AI systems in putting in place the adequate safeguards referred to in this paragraph.

Article 15
Accuracy, robustness and cybersecurity

1a. (new) To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 of this Article, the AI Office shall bring together national and international metrology and benchmarking authorities and provide non-binding guidance on the matter as set out in Article 56, paragraph 2, point (a).

Obtenu par CONTEXTE

Article 58
Tasks of the Office

(ca) (new) provide interpretive guidance on how the AI Act applies to the ever evolving typology of AI value chains, and what the resulting implications in terms of accountability of all the entities involved will be under the different scenarios based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards;

(cb) provide particular oversight and monitoring and institutionalize regular dialogue with the providers of foundation models about the compliance of foundation models as well as AI systems that make use of such AI models with Article 28b of this Regulation, and about industry best practices for self-governance. Any such meeting shall be open to national supervisory authorities, notified bodies and market surveillance authorities to attend and contribute

(cd) issue and periodically update guidelines on the thresholds that qualify training a foundation model as a large training run, record and monitor known instances of large training runs, and issue an annual report on the state of play in the development, proliferation, and use of foundation models alongside policy options to address risks and opportunities specific to foundation models.

Article 58a (new)
Benchmarking

The European authorities on benchmarking referred to in Article 15 (1a) and the AI Office shall, in close cooperation with international partners, jointly develop cost-effective guidance and capabilities to measure and benchmark aspects of AI systems, and notably of foundation models relevant to the compliance and enforcement of this Regulation based on the generally acknowledged state of the art, including as reflected in relevant harmonized standards.

ANNEX VIII

Section C - The following information shall be provided and thereafter kept up to date with regard to foundation models to be registered in accordance with Article 28b (e).

1. ***Name, address and contact details of the provider;***
2. ***Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;***
3. ***Name, address and contact details of the authorised representative, where applicable;***
4. ***Trade name and any additional unambiguous reference allowing the identification of the foundation model ;***

Obtenu par CONTEXTE

5. ***Description of the data sources used in the developmentof the foundation model ;***
6. ***Description of the capabilities and limitations of the foundation model , including the reasonably foreseeable risks and the measures that have been taken to mitigate them as well as remaining non-mitigated risks with an explanation on the reason why they cannot be mitigated***
7. ***Description of the training resources used by the foundation model including computing power required, training time, and other relevant information related to the size and power of the model***
8. ***Description of the model's performance, including on public benchmarks or state of the art industry benchmarks***
9. ***Description of the results of relevant internal and external testing and optimisation of the model***
10. ***Member States in which the foundation model is or has been placed on the market, put into service or made available in the Union;***
11. ***URL for additional information (optional).***

12.

Obtenu par CONTEXTE