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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Telecommunications and Information Society
Subject:	Artificial Intelligence Act - FR comments Articles 1-29, Annexes I-IV (doc. 8115/21)

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (15.03.2022)

Delegations will find in annex FR comments on Artificial Intelligence Act (Articles 1-29, Annexes I-IV).

Commission proposal (doc. 8115/21 – COM(2021) 206 final) Deadline for comments: **26 *October 2021***

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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Commission proposal	Drafting Suggestions	Comments
2021/0106 (COD) **Proposal for a** **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS**	**(New) This Regulation is without prejudice to Article 4(2) of the TEU.** **(New) This Regulation recognises the importance of justified, proportionate and controlled use of AI for important objectives of general public interest of the Union or of a Member State, such as the protection of the public and security. The use of AI for such objectives should be allowed.** **(New) The transparency and compliance obligations established by this Regulation should not lead to the publication of information the**	

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	secrecy of which is necessary for the preservation of the public interest . [redacted] (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	

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	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 not physical spaces. **This wording does not extend to correctional institutions.** 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.	COM replied to FR's question about correctional institutions, saying that it did not consider them to be publicly accessible spaces. It is believed that this exclusion needs to appear at least in the recitals. We suggest either "*correctional institutions*" or "*prison premisces*".

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	Consequently, in addition to public spaces such as streets, relevant parts of government buildings and most transport infrastructure, spaces such as cinemas, theatres, 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. (12) This Regulation should also apply to Union institutions, offices, bodies and agencies when acting as a provider or user of an AI system. **~~AI systems~~**	

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	~~**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).**~~ [redacted]	According to COM, national security is out of the regulations's scope by nature. However, several institutions fear that ECJ would interpret it differently if this is not expressly mentioned. We could also be open to another phrasing

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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	[redacted] 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].	
TITLE I		
GENERAL PROVISIONS		

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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Article 1 Subject matter		
This Regulation lays down:		
(a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems (‘AI systems’) in the Union;		
(a) prohibitions of certain artificial intelligence practices;		
(b) specific requirements for high-risk AI systems and obligations for operators of such systems;		

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(c) harmonised transparency rules for 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;		
(d) rules on market monitoring and surveillance.		
	New article **This Regulation is without prejudice to Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088**	The regulation gives a framework and sets criteria to determine if aaaand how an economica financial activity can be qualified as "*environmentally sustainable*".is "green" or not. The chapter II of this regulation targets

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		environmentally sustainable economic activities and specifically climate change.
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;		
(b) users of AI systems located within the Union;		

(c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union;		
2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts, only Article 84 of this Regulation shall apply:		
(a) Regulation (EC) 300/2008;		
(b) Regulation (EU) No 167/2013;		
(c) Regulation (EU) No 168/2013;		
(d) Directive 2014/90/EU;		

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(e) Directive (EU) 2016/797;		
(f) Regulation (EU) 2018/858;		
(g) Regulation (EU) 2018/1139;		
(h) Regulation (EU) 2019/2144.		
3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.	3. This Regulation shall not apply to AI systems **whose** ~~**developed**~~ **development or use falls outside the application of Union law, and in any event, AI systems developed** or used**,** exclusively [redacted] for ~~**military**~~ **for national security and defence** purposes**,** [redacted]	EU has no competence regarding national security (Article 4 TFEU). However, national security applications are not explicitly excluded from the scope of the regulation. This issue remains unclear, particularly regarding real-time remote biometric identification in public spaces for law enforcement purposes. Indeed, this type of use of

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	[redacted]	the system is prohibited by the Regulation (Article 5(d)), except in certain derogatory cases, which include" the prevention of a terrorist attack" (Article (d)(ii)). The administrative field of intelligence is thus clearly identified as a possible derogatory case. It is thus important to explicitly exclude intelligence services from the users covered by the Regulation.
4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for		

law enforcement and judicial cooperation with the Union or with one or more Member States.		
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*].		
Article 3 Definitions		

[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).

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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For the purpose of this Regulation, the following definitions apply:		
(1) ‘artificial intelligence system’ (AI system) means 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;		
(1) ‘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	(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~~be placed** on the market or **put~~ting it~~** into service under its	“*with a view to*” is a very extensive notion that will cause interpretation problems , and that, in certain cases, may be understood as applying to R&D or to open source developments.

own name or trademark, whether for payment or free of charge;	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[2];		
(4) 'user' means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;		It might be appropriate for the Commission to clarify the envisaged cumulative application of the different definitions provided for in the AI Regulation and in the Medical Devices Regulation, in particular. Indeed, FR has underlined an additional remark concerning the discrepancies between the definitions of "*user*" and "*operator*" in both of the regulations on AI

[2] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

		and MD, which can result in making impossible a "cumulative" application of the requirements of these two regulations for operators, as initially envisaged by the Commission. The definition of "*user*" in this proposal excludes the layman. However, the Medical Devices Regulation includes this difference between two definitions, but this deifference is not taken into account in this proposal. Thus in AI Regulation: "user" means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the context of a personal non-professional activity. In DM Regulation: "*user*" is any health professional or lay person who uses a device.

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		In DM Regulation, "*economic operator*" means a manufacturer, agent, importer, distributor or the person referred to in Article 22(1) and 22(3).
(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;		
(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;		

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(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 authorised representative, the importer and the distributor;		This proposal includes the definition of users. It’s not the case in Medical Devices Regulation, as there is a distinction between operators and users. IA Regulation: "*operator*" means supplier, user, authorized representative, importer and distributor.
(9) ‘placing on the market’ means the first making available of an AI system on the Union market;		

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(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 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, but which may result from reasonably foreseeable human behaviour or interaction with other systems;		
(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;		

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(15) 'instructions for use' means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use, 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 made available to users;		
(17) 'withdrawal of an AI system' means any measure aimed at preventing the distribution, display and offer of an AI system;		

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(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 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 in accordance with this Regulation and other relevant Union harmonisation legislation;		
(23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;		

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(24) 'CE marking of conformity' (CE marking) means a marking by which a provider indicates that an 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;		

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(26) 'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020;		
(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 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;		
(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 overfitting; whereas the validation dataset can 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 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;		
(34) ‘emotion recognition system’ means an AI system for the purpose of identifying or		

inferring emotions or intentions of natural persons on the basis of their biometric data;		
(35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;		
(36) ‘remote biometric identification system’ means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person’s biometric data with the biometric data contained in a reference database, and without prior knowledge of the		

user of the AI system whether the person will be present and can be identified ;		
(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.		
(38) ‘‘post’ remote biometric identification system’ means a remote biometric identification system other than a ‘real-time’ remote biometric identification system;		

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(39) 'publicly accessible space' means any physical place accessible to the public, regardless of whether certain conditions for access may apply;		
(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		

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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 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 authority to which a Member State assigns the responsibility for the implementation and		

application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board;		
(43) ‘national competent authority’ means the national supervisory authority, the notifying authority and the market surveillance authority;		
(44) ‘serious incident’ means any incident that directly or indirectly leads, might have led or might lead to any of the following:		

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(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.		
	Additional paragraph **Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, and where the same term is also defined in the legal acts listed in Annex II, Section A, both definitions apply.**	A number of definitions on identical terms included in Regulation 2017/745/EU on medical devices and in Regulation 2017/746/EU on in vitro diagnostic medical devices are different from those mentionned in the present proposal. All these definitions are not contradictory, but which definition applies is not clear for all the actors involved.
Article 4 Amendments to Annex I		

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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.		
TITLE II		
PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES		
Article 5		

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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

a manner that causes or is likely to cause that person or another person physical or psychological harm;		
(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following:		
(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the		

contexts in which the data was originally generated or collected;		
(ii) detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is 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:		The use of such technology for law enforcement purposes is no more restricted than its use by the private sector. It must therefore be strictly limited, *proportionate* to several criteria, and not subject to a list of necessary conditions.
(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;		Ongoing work by FR experts
(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/JHA[3] 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.		

[3] 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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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;	(a) the nature of the situation giving rise to the possible use, in particular the seriousness, potentiality **~~probability~~** and scale of the harm caused in the absence of the use of the system;	Evaluating the probability of damage caused by the absence of a system is very difficult to achieve in homeland security. The probability assumes a measurable character, which is not possible here.
(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.	(b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness,	

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	potentiality ~~probability~~ and scale of those consequences.	
In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations.		Ongoing work by FR experts
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.		
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.		
TITLE III		
HIGH-RISK AI SYSTEMS		
Chapter 1		

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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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 is itself a product, covered by the Union harmonisation legislation listed in Annex II;		

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.		
2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.	2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems**, posing a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights,** referred to in Annex III shall also be considered high-risk.	Only AI systems that may present a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights should be considered as high-risk. Furthermore, the same criteria should be applied to draw and amend the list of Annex III.

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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 Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:	The Commission is empowered to adopt ~~delegated~~ **implementing** acts **every XX years,** in accordance with Article ~~73~~ **XXXX** to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:	It is not a question of amending an essential element of the legislative act, but rather of its application. Only the Council should therefore intervene, among the co-legislators. Moreover, it is convenient to provide for a fixed periodicity of revision of the list, in order to keep control over this revision. If the necessity to be able to modify this annex rapidly, considering the very important technological progress in this sector, it is nevertheless problematic that the Member States are not associated in the decision process, which will have very important consequences on the work of their services. It would be preferable and

		essential to allow the Commission to modify Annex III by means of implementing acts, thus allowing prior consultation of the Member States.
(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;		
(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.		

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2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria:		
(a) the intended purpose of the AI system;		
(b) the extent to which an AI system has been used or is likely to be used;		
(c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental		

rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities;		
(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;		
(e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;		

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(f) the extent to which potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, or age;		
(g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;		
(h) the extent to which existing Union legislation provides for:		

(i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;		
(ii) effective measures to prevent or substantially minimise those risks.		
Chapter 2		
REQUIREMENTS FOR HIGH-RISK AI SYSTEMS		
Article 8 Compliance with the requirements		
1. High-risk AI systems shall comply with the requirements established in this Chapter.		

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2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.		
	(New) **3. When some of the requirements laid out in articles 8 to 15 may enter into conflict, the development of AI systems can adopt a balancing approach between them. The balance should be explicit**	We should adopt a holistic approach to risk mitigation. Some of the 7 key requirements identified by the HLEG on AI are often at odds, leading to unavoidable trade offs; for instance accuracy vs robustness, privacy (data minimization) vs fairness, or accuracy vs fairness etc. However, the balance made has to be assumed and could be part of explainibility in Article 13.1.
Article 9 Risk management system		

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1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.		
2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:		
(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;		
(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;		
(c) evaluation of other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;		
(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.		
3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this		

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

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In identifying the most appropriate risk management measures, the following shall be ensured:		
(a) elimination or reduction of risks as far as possible through adequate design and development;		
(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;		
(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.		

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In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.		
5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.		

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6. 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.		
7. 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, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.		
8. When implementing the risk management system described in paragraphs 1		

to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.		
9. For credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.		
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 developed on the basis of training,		

validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.		
2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,		
(a) the relevant design choices;		
(b) data collection;		
(c) relevant data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;		

(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;		
(e) a prior assessment of the availability, quantity and suitability of the data sets that are needed;		
(f) examination in view of possible biases;		
(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.		
3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate	3. Training, validation and testing data sets shall be relevant, **sufficiently** representative, ~~free of errors and complete. They shall have the~~	Practically impossible to be free of errors or complete.

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statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.	~~appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof~~**and curated with best proportionate efforts given the nature of the system and the state of the art.**	
4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.		

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

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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.		
	(New) **7. In order to comply with the requirements laid out in this article, the minimization principle shall be interpreted with consideration for the full life cycle of the system.**	The minimization principle laid out in GDPR and its interpretation by EDPB shall take into account the necessity to retain some training evaluation and testing data, during the whole life cycle of the system.
Article 11 Technical documentation		

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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 competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.		
2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex		

II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.		
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.		
Article 12 Record-keeping		

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1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.		
2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the 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.		
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;		

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(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).		
Article 13 Transparency and provision of information to users		
1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to	High-risk AI systems shall be designed and developed in such a way to ensure that their operation is ~~sufficiently~~ **as much as possible** transparent ~~to enable users to interpret the system's output and use it appropriately~~. An appropriate type and degree of transparency shall	In most HR AI systems, it is difficult to fully interpret the way that the output has been reached. Full interpretability is often impossible, but we can rely on "best degree of transparency"

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achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.	be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title **and to enabling users to understand and use the system appropriately**.	
2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.		
3. The information referred to in paragraph 2 shall specify:		

(a) the identity and the contact details of the provider and, where applicable, of its authorised representative;		
(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:		
(i) its intended purpose;		
(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;		

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(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;	(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or ~~under conditions of reasonably foreseeable misuse~~, which may lead to risks to the health and safety ~~or fundamental rights~~;	It is too difficult to predict cases of possible misuse
(iv) its performance as regards the persons or groups of persons on which the system is intended to be used;		
(v) when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.		

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(c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;		
(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users;		
(e) the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates.		

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Article 14 Human oversight		
1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.		
2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular		

when such risks persist notwithstanding the application of other requirements set out in this Chapter.		
3. Human oversight shall be ensured through either one or all of the following measures:		
(a) identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;		
(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user.		

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4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:		
(a) fully understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;		
(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system (‘automation bias’), in particular for high-risk		

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AI systems used to provide information or recommendations for decisions to be taken by natural persons;		
(c) be able to correctly interpret the high-risk AI system's output, taking into account in particular the characteristics of the system and the interpretation tools and methods available;		
(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;		
(e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a "stop" button or a similar procedure.		

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5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.	5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least ~~two~~ **one** natural persons.	Burdensome, we could limit this to one natural person. In principle, human verification and confirmation seems acceptable. However, despite COM's explanation on the "four eyes" rule, this will require some kind of procedural formalization in order to be adequately registered in the records. Therefore, it would be relevant to leave some latitude to MS in the practical application of this principle. We believe that in terms of allocation of human resources and of practical application of that obligation, verification by two persons is excessive.
Article 15 Accuracy, robustness and cybersecurity		

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.		
2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.		
3. High-risk AI systems shall be resilient as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to		

their interaction with natural persons or other systems.		
The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.		
High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs due to outputs used as an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.		

4. High-risk AI systems shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities.		
The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.		
The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset (‘data poisoning’), inputs designed to cause the model to make a mistake (‘adversarial examples’), or model flaws.		

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Chapter 3		
OBLIGATIONS OF PROVIDERS AND USERS 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:		
(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;		

(b) have a quality management system in place which complies with Article 17;		
(c) draw-up the technical documentation of the high-risk AI system;		
(d) when under their control, keep the logs automatically generated by their high-risk AI systems;		
(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;		Ongoing work by FR experts.
(f) comply with the registration obligations referred to in Article 51;		

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(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;		
(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;		
(i) to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;		

(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.		
Article 17 Quality management system		
1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and 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;		
(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, 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 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 market or putting into service 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;		

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

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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.		

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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.		Ongoing work by FR experts.

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.		
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. The logs shall be kept for a period that is		

appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.		
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.		
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 take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.		
Article 22 Duty of information		
Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent 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 of the non-compliance and of any corrective actions taken.		
Article 23 Cooperation with competent authorities		
Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned		

request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.		
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.		
Article 25 Authorised representatives		
1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	1. Prior to making their systems available on the Union market, ~~where an importer cannot be identified,~~ providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	The appointment of an authorised representative has to be foreseen where the provider is established outside the EU

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2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:		
	Additional paragraph **3. 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 together under the responsibility of an authorised representative, the authorised representative of the product shall fulfil the obligations imposed by the present Regulation on the authorised representative, together with the obligations imposed in the specific legal act listed in Annex II, Section A.**	The obligations of authorised representative under Regulation 2017/745/EU on medical devices and under Regulation 2017/746/EU on in vitro diagnostic medical devices are different from those mentionned in the present proposal. All these obligations are not contradictory but the legal obligations of each economic operator have to be clearly stated.

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(a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);		
(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;		

(c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.		
Article 26 Obligations of importers		
1. Before placing a high-risk AI system on the market, importers of such system shall ensure that:		
(a) the appropriate conformity assessment procedure has been carried out by the provider of that AI system		

(b) the provider has drawn up the technical documentation in accordance with Annex IV;		
(c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.		
2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, 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, on its packaging or its accompanying documentation, as 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 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 that national competent authority, 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. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.		
	Additional paragraph **6. 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 under the responsibility of an authorised**	The obligations of importers under Regulation 2017/745/EU on medical devices and under Regulation 2017/746/EU on in vitro diagnostic medical devices are different from those mentionned in the present proposal. All these

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	representative, the authorised representative of the product shall fulfil the obligations imposed by the present Regulation on the authorised representative, together with the obligations imposed on the authorised representative in the specific legal act listed in Annex II, Section A.	obligations are not contradictory but the legal obligations of each economic operator have to be clearly stated.
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 obligations set out in this Regulation.		
2. Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.		

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

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	Additional paragraph **6. 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 under the responsibility of a distributor, the distributor of the product shall fulfil the obligations imposed by the present Regulation on the distributor, together with the obligations imposed on the distributor in the specific legal act listed in Annex II, Section A.**	The obligations of distributors under Regulation 2017/745/EU on medical devices and under Regulation 2017/746/EU on in vitro diagnostic medical devices are different from those mentionned in the present proposal. All these obligations are not contradictory but the legal obligations of each economic operator have to be clearly stated
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;	(a) they place on the market or put into service a high-risk AI system under their name or trademark**, except in cases where a distributor or importer enters into an agreement with a provider whereby the provider is identified as such on the label and is responsible for meeting the requirements placed providers in this Regulation**;	
(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;		

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(c) they make a substantial modification to the high-risk AI system.	(c) they make a substantial modification to the high-risk AI system**, in such a way that compliance with the applicable requirements may be affected**.	
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.		
Article 29 Obligations of users of high-risk AI systems		
1. Users of high-risk AI systems shall use such systems in accordance with the instructions		

of use accompanying the systems, pursuant to paragraphs 2 and 5.		
2. The obligations in paragraph 1 are without prejudice to other user obligations under Union or national law and to the user's discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.		
3. Without prejudice to paragraph 1, to the extent the user exercises control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system.		

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4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. In case the user is not able to reach the provider, Article 62 shall apply mutatis mutandis.		

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

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

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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;	~~Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;~~	The proposed definition is too broad. We could potentially remove point b completely in order to narrow the definition (or, at least, only for the applications covered under annex II where we already have some sectorial regulations)

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

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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);		
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		
1. 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).		
2. 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);		
3. 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);		

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4. 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);		
5. 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).		
6. 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);		
7. 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.		

Artificial Intelligence Act (Articles 1-29, Annexes I-IV)

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ANNEX III **HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)**		
High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:		Ongoing work by FR experts.
1. Biometric identification and categorisation of natural persons:		Ongoing work by FR experts.
(a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons;		Ongoing work by FR experts.

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2. Management and operation of critical infrastructure:		Ongoing work by FR experts.
(a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.		Ongoing work by FR experts.
3. Education and vocational training:		
(a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;		

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(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 educational institutions.		
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 advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;	(a) AI systems intended to be used for recruitment or selection of natural persons, ~~notably for advertising vacancies~~, screening or filtering applications, evaluating candidates in the course of interviews or tests;	Not all task allocation should fall under high risk.

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(b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.	AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation **based on individual behavior** and for monitoring and evaluating performance and behavior of persons in such relationships.	
5. Access to and enjoyment of essential private services and public services and benefits:		
(a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well		

as to grant, reduce, revoke, or reclaim such benefits and services;		
(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 put into service by small scale providers for their own use;		
(c) AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid.		
6. Law enforcement:		

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(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;	(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 **a natural person to become a** potential victim~~s~~ of criminal offences;	The risk for potential victims of criminal offences does not involve personal data to be protected (either on the part of the respondent or the victim).
(b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;		Ongoing work by FR experts.

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(c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);		Ongoing work by FR experts.
(d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;	d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences **without posterior human evaluation**;	This restriction may question the effectiveness of criminal investigations, the reliability of evidence in the judicial field (images, DNA, etc.).
(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		Ongoing work by FR experts.

personality traits and characteristics or past criminal behaviour of natural persons or groups;		
(f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;		
(g) AI systems intended to be used 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	(g) AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search related and unrelated large data sets available in different data sources or in different data formats in order	These systems are not very risky: they either find an objective link between data or they find none. Criminal analysis would be restricted by this point. Thus, the analysis of criminal group exchanges, as was the case in the EncroChat case,

formats in order to identify unknown patterns or discover hidden relationships in the data.	to identify **high complex** unknown patterns or discover hidden relationships in the data.	will be made difficult given the mass of data involved. The idea of the alternative wording, which shifts the word "*complex*" to the result of the data crossing rather than to the complexity of the data itself, is to reserve this definition of application to HR to the complex highlighting of certain data containing an element of predictability/ prospecting (e.g., a tool revealing complex money laundering operations using numerous foreign accounts based on known patterns) in order to exclude from this classification the "*simple*" tools that already exist and that do not contain any prospecting, but merely search for identical data that may appear in different formats (e.g., reading a license plate, etc.)

		reading a license plate; analysis of geolocation data...).
7. Migration, asylum and border control management:		
(a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;		Ongoing work by FR experts.
(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural		Ongoing work by FR experts.

person who intends to enter or has entered into the territory of a Member State;		
(c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;	AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features **without posterior human evaluation**;	The detection of false documents is not in itself a high risk. It is a common practice of the security forces concerned and is always corroborated by manual analysis.
(d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.		

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8. Administration of justice and democratic processes:		
(a) AI systems intended to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts.	(a) AI systems intended to assist a judicial authority ~~in researching and interpreting facts and the law and~~ in applying the law to a concrete set of facts.	We thank COM for the explanations given, but we still believe this is not clear enough to be applied consistently by MS.
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, the person/s developing the system the date and the version of the system;		
(b) how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable;		

(c) the versions of relevant software or firmware and any requirement related to version update;		
(d) the description of all forms in which the AI system is 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;		

(g) instructions of use for the user and, where applicable installation instructions;		
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) the design specifications of the system, namely the general logic of the AI system and		

of the algorithms; 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;		

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(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, in accordance with Articles 13(3)(d);		
(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 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).		
3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended		

outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;		
4. A detailed description of the risk management system in accordance with Article 9;		
5. A description of any change made to the system through its lifecycle;		

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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 other relevant standards and technical specifications applied;		
7. A copy of the EU declaration of conformity;		
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).		
	End	**End**