Council of the European Union
General Secretariat

Brussels, 08 November 2021

WK 13348/2021 INIT

LIMITE

TELECOM

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

CONTRIBUTION

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

Delegations will find in annex PT 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)

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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**		
TITLE I		
GENERAL PROVISIONS		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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) prohibitions of certain artificial intelligence practices;	
(b) specific requirements for high-risk AI systems and obligations for operators of such systems;	(c) specific requirements for high-risk AI systems and obligations for operators of such systems;	

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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) harmonised transparency rules for AI systems intended to interact with natural persons, including emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content, and automatic decision systems/algorithms (credit assignment, social benefits, insurances, etc.) that have a considerable impact in people's lives;	
(d) rules on market monitoring and surveillance.	(e) rules on market monitoring and surveillance.	
Article 2 Scope		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

1. This Regulation applies to:		It came to our attention that AI researchers and software developers regularly upload AI models and other AI related materials to repositories, which have a critical and beneficial role in the software ecosystem. Therefore, given the wording of this article there is a risk that those who upload these materials to software repositories (e.g. open-source), or the operators of these repositories, could be viewed as a regulated entity without "placing on the market" or "putting into service" the system in the EU, which might have an impact on research and open-source software innovation on the EU. Consequently, we recommend that the terms "placing on the market" and "putting into service" should specifically exclude use of AI systems for internal research and development purposes.
(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:		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes.		
4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international 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		General remark regarding definitions: the regulation should, where possible, facilitate cooperation both at the domestic level (between MS) but also at the international level. As such, all definitions used should, in so far as possible, be compatible with similar definitions used in other relevant instruments on AI.
For the purpose of this Regulation, the following definitions apply:		We kindly recommend ensuring that the definitions are set in alphabetic order with the

[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).

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		aim of facilitating its reading, analysis, and application
(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;	Ex.1: OECD definition of AI system – *a machine-based system that is capable of influencing the environment by producing an output (predictions, recommendations or decisions) for a given set of objectives. It uses machine and/or human-based data and inputs to (i) perceive real and/or virtual environments; (ii) abstract these perceptions into models through analysis in an automated manner (e.g., with machine learning), or manually; and (iii) use model inference to formulate options for outcomes. AI systems are designed to operate with varying levels of autonomy.*	We suggest using the AI definition made by the High-Level Expert Group on Artificial Intelligence: (ex2) Despite the remarkable effort made by the Commission in this context, we consider that the construction of the concept of 'Artificial intelligence system', as laid down in Article 3(1), deserves some remarks. Starting by noting that the first objective of the proposal is precisely to "ensure that AI systems placed on the Union market and used are safe and comply with existing legislation on fundamental rights and Union values", the concrete definition of what is meant by

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

	Ex2.: The definition proposed by the High-Level Expert Group on Artificial Intelligence: *Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications).*	"Artificial Intelligence" plays a central role as it is the basis for the specific definition of all normative solutions included in the Proposal. Based on this premise, the solution adopted in the Proposal - which is based on the concept of "Artificial Intelligence System" - should adequately reflect the concern, expressed in Recital 6, according to which the definition to be adopted "(…) should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments [and] (…) be based on the key functional characteristics of the software, in particular the ability, for a given set of human-defined objectives, to generate outputs such as content, predictions, recommendations, or decisions which influence the environment with

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		which the system interacts, be it in a physical or digital dimension." Considering the architecture built on the basis of Article 3(1) and its dynamic interaction with Annex I, we are not convinced that these conditions have been effectively achieved. By referring to the "techniques and approaches listed in Annex I", the definition relies on the accuracy of the list inserted therein. The problem is, in our view, that both provisions considered, we would have an absurdly vague definition: if the specific purpose of Annex I was to complete the definition by specifying which techniques and approaches constitute techniques and approaches in the field of artificial intelligence, it completely misses the point by enabling the inclusion of practically all

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		computational techniques and approaches (machine learning, inductive and deductive logic, and statistical approaches). Since the title of Annex I refers to "Artificial Intelligence Techniques and Approaches," it could be assumed that the definition of, for example, 'logic-based approaches' is limited to logic-based approaches to artificial intelligence. However, as we have indicated above, since 'artificial intelligence' is defined as any algorithm which uses the techniques listed in Annex I, this specification has become circular and is therefore not a specification at all. Given the paramount importance of this definition and the inherent need for it to be technically robust enough to confer a degree of legal certainty compatible with the legal

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		principles and values to be guaranteed by the proposed framework, it will be essential, we believe, to rethink this definition. The possible solution will be to carry out a comparative study of the definitions already advanced in the various fora which best takes into account these requirements.
(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 own name or trademark, whether for payment or free of charge;	(~~1~~2) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge;	This notion appears to consider that all AI systems are developed as a stand-alone product or service and then “placed on the market”/ ”put into service”. Whereas the AI ecosystem is very diverse and there are many ways AI systems are developed and deployed, and there is almost never a singular entity or person that develops an AI system. AI systems are the result of numerous entities building on top of others’ efforts, for

		example it may start by using open-source repositories created by several contributors and the resulting model might then be shared under an open-source licence for others to build on. Therefore, we should ask ourselves "who among all the contributors "develops an AI system?" It is of paramount importance to consider the range of developers, researchers, and innovators that make up the open-source community, which has been crucial to advancing the state-of-the-art of AI development. We need a more nuanced taxonomy to identify the relevant participants in the AI ecosystem and allocate the appropriate responsibilities and

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		obligations to each one rather than a definition of "provider" that risks treating all contributions big and small to the same burdensome regulatory standards irrespective of their nature and role. Please consider correcting this small typo.
(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		

[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).

AI system is used in the course of a personal non-professional activity;		
(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		
(9) ‘placing on the market’ means the first making available of an AI system on the Union market;		
(10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		
(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		We propose to clarify the definition "instructions for use" given the fact that we believe that this definition creates legal uncertainty regarding its scope. The

geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;		"instructions for use" appear to be only applicable to "high risk AI" systems when these are useful and desirable for all AI systems as they are for other types of software.
(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;		
(18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		We believe this term needs further clarification.
(24) 'CE marking of conformity' (CE marking) means a marking by which a provider indicates that an AI system is in conformity with		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products ('Union harmonisation legislation') providing for its affixing;		
(25) 'post-market monitoring' means all activities carried out by providers of AI systems to proactively collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;		
(26) 'market surveillance authority' means the national authority carrying out the activities		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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 ;		In our opinion, it is also unclear the scope of this definition. The use of this system can pose risks to fundamental rights but can also have positive social benefits, such as monitor health and safety. Consequently, we recommend clarifying certain aspects to enable positive uses of this system. Further, it is not understandable the meaning of identifying natural persons "at a distance",

		especially taking into account that high risk uses of remote biometric identification cover, not only "real-time" but also "post" identification, and so it raises the doubt as how can the identification be made "after the fact" in any other way other than "at a distance". It seems that the intention was to cover mass surveillance "where "many people are being screened simultaneously" but the language should be clarified to reflect that intent. Otherwise, commonplace AI systems that identify natural persons at a distance such as smartphones used to identify friends in photos are also regulated under this provision. Moreover, it is also not clear the intention behind the exclusion from the definition "where the "user of the AI system" has "prior knowledge ...whether the person will

		be present and can be identified." For example, consumers might use their smartphone's AI to find in their photos the faces of family and friends that they trained their device to recognise. In that example, it is unclear who the user of the AI system is. If the consumers are users, they arguably have "prior knowledge" whether the individuals in their contacts or their photo album can be identified by the device. But if the "user of the AI system" is the smartphone or software vendor that designed the AI system for the device, would they have prior knowledge? The language of this article should be clarified in order to not prevent common and beneficial uses of AI to which people would be willing to consent, if given the appropriate opportunity."

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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	(b) any **national security and intelligence agency** or other body or entity entrusted by	In order to prevent loopholes undermining the prohibition on real-time remote biometric

and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;	identification, the use of AI systems by national security and intelligence agencies should be specifically included in this provision.
(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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:		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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.		
	”Personal data” means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic,	We propose to include a definition of “personal data” in line with the Regulation (EU) 2017/679 of the European Parliament and of the Council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) given the fact that this concept is used several times in

	mental, economic, cultural or social identity of that natural person.	the proposed text and that is included in the text a definition of "biometric data".
Article 4 Amendments to Annex I		
The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.		
TITLE II		
PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

Article 5		
1. The following artificial intelligence practices shall be prohibited:		
(a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness 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		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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:		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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:		

(i) the targeted search for specific potential victims of crime, including missing children;		
(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack;		
(iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[3] and punishable in the Member State concerned by a custodial sentence or a detention order for a		

[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).

maximum period of at least three years, as determined by the law of that Member State.		
2. The use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:		
(a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system;		
(b) the consequences of the use of the system for the rights and freedoms of all persons		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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)

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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.		
Article 7 Amendments to Annex III		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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:	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:~~	As it now stands, the regulation only allows the inclusion of new high-risk AI systems if they fall under any of the eight listed areas and are deemed to pose at least as great a risk (to health and safety or adverse impact on fundamental rights) as systems already in Annex III. In our opinion, while the eight domains listed seem broad enough, there is a real possibility that they are unable to exhaust the range of domains within which AI systems may have significant impacts on the individual's lives in the future. AI systems' use in various other domains could raise significant additional risks that are not sufficiently encompassed in these eight risk areas (one example: AI-based personal digital assistants which could be used to give individuals important financial, legal, or medical advice with

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		significant consequences for health and safety, and do not appear to be covered by the current risk categories). There is also the natural and rapid evolution of these systems, a reality which in itself makes the extent of its impacts very difficult to anticipate.
(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;	~~(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,	~~(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	

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.	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	
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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		
(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

Article 8 Compliance with the requirements		
1. High-risk AI systems shall comply with the requirements established in this Chapter.		
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.		
Article 9 Risk management system		As a general comment, we believe that the risks this article intends to address with the recitals, that explicitly state the importance of addressing risks to health, safety, and fundamental rights, should be more harmonized. Furthermore, we

		consider to be of paramount importance to be very clear on the types of risks we are attempting to address and define clear procedures to help guide providers, developers, etc through the risk assessment process. Additionally, it is important to stress out the need to define the concept "lifecycle", which is used in this article, as well as in several others. The undefinition of this concept will create legal uncertainty and confusion. Moreover, and as referred above AI products/systems are generally created by several contributors and usually using open-source technologies and as so it is necessary to define how the risks in these cases will be managed, e.g. will the person who used

		the open-source materials be responsible/liable for the materials used? Or will be the person who created the open-source material? Finally, considering the principles of the New Legislative Framework it seems that AI system providers will carry most obligations and requirements established in the proposed Regulation. Nevertheless, it is important to keep in mind that many obligations and requirements can only be managed, in practice, by the user (who controls the AI system and its use). Even if a provider complies with all its obligations and requirements it cannot foresee all potential uses of the system

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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 broader societal harms, beyond risks to health and safety or fundamental rights;**	While most risks from AI technology can be thought of as the potential for harms to an individual's health and safety or of adverse impact on their fundamental rights, AI may also cause significant harm, on a societal level (for example, a digital personal assistant could be used to promote certain products, services, or even ideologies well above others, with the potential to contribute to substantial and potentially harmful shifts in our markets, democracies, and information ecosystems). However, the impacts on individual health, safety, or fundamental rights may be difficult to determine. Adding an extra step to this risk

		management system requiring evaluation of broader societal harms from AI systems would ensure that these risks are duly assessed by the providers of AI systems.
(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 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.		It is established that mitigation should be used until the "overall residual risk of the high-risk AI system is judged acceptable", once again, is not clear what it means "acceptable". Therefore, we consider it is necessary to develop best practices and standards to define these concepts in the proposed regulation.

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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		This number covers "testing procedures" but it is not clear which type of testing they are referring to. The lack of specification will create misunderstandings, legal uncertainty, and confusion. There are several types of test procedures, such as, unit tests, integration tests, performance tests, operational tests, etc. These tests are of paramount importance and its use will help to mitigate the risks.

		Hence, we suggest adding an article to regulate the test phase of AI solutions in order to mitigate the risks of AI. Additionally, we also propose to mention technics such as Explainable Artificial Intelligence (XAI), referred in the EC Communication regarding Artificial Intelligence for Europe. The use of these technics should be encouraged given the fact that these can help debugging and auditing activities. A new article is proposed further in this document
6. Testing procedures shall be suitable to achieve the intended purpose of the AI system		It is not explained what it means to be “suitable” and due to the fact, there are no best practices or

and do not need to go beyond what is necessary to achieve that purpose.		standards, as there are for instance for data protection, the use of these terms will create legal uncertainty and as so we recommend to develop standards and best practices to define these concepts. This number covers "testing procedures" but it is not clear which type of testing they are referring to. The lack of specification will create misunderstandings, legal uncertainty, and confusion. There are several types of test procedures, such as, unit tests, integration tests, performance tests, operational tests, etc. These tests are of paramount importance and its use will help to mitigate the risks. Hence, we suggest adding an article to regulate the test phase of AI solutions in order to mitigate

		the risks of AI. Additionally, we also propose to mention technics such as Explainable Artificial Intelligence (XAI), referred in the EC Communication regarding Artificial Intelligence for Europe. The use of these technics should be encouraged given the fact that these can help debugging and auditing activities. A new article is proposed further in this document
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		This number covers "testing procedures" but it is not clear which type of testing they are referring to. The lack of specification will create misunderstandings, legal uncertainty, and confusion. There are several types of test

be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.		procedures, such as, unit tests, integration tests, performance tests, operational tests, etc. These tests are of paramount importance and its use will help to mitigate the risks. Hence, we suggest adding an article to regulate the test phase of AI solutions in order to mitigate the risks of AI. Additionally, we also propose to mention technics such as Explainable Artificial Intelligence (XAI), referred in the EC Communication regarding Artificial Intelligence for Europe. The use of these technics should be encouraged given the fact that these can help debugging and auditing activities. A new article is proposed further in this document

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		
	10. Appropriate meaningful explanations shall apply for the development of high-risk AI systems in order to increase the user benefit, the social acceptance, the assisting with audits for compliance with regulations, and system	We propose to mention technics such as Explainable Artificial Intelligence (XAI), referred in the EC Communication regarding Artificial Intelligence for Europe . The use of these technics should be encouraged given the

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

	debugging, and the support of field testing reerred in to Article XX (new proposed article futher in this document)	fact that these can help the debugging and auditing activities previous to the deployment and need for human oversight.
Article 10 Data and data governance		General remark: In our opinion, the repeated use of the term "appropriate" in several provisions of this Article may result in excessive imprecisions and legal uncertainty: in paragraphs 2 and 6 (***appropriate*** *data governance*), in paragraph 3 (***appropriate*** *statistical properties*) and in paragraph 5 (***appropriate*** *safeguards for the fundamental rights and freedoms of natural persons*). For example, it is very difficult to know particularly what constitutes an "adequate" statistical property: does this require the data to be a representative sample of the entire population, or only of the potential *ad hoc* groups that may be subjected to the AI system's analysis? This

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		decision is thus left to the respective provider, who will thus make the realisation as he sees fit.
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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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 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.	Training, validation and testing data sets shall ~~be relevant, representative, free of errors and complete. They shall~~ have the 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, as well as, the appropriate statistical properties to be included as the requirements refferred to in Article 13(2) and to help the interpretation of the system behaviour in the utilization phase tasks reffered to in Article 14.	The entire data collection and data management process may include access to old data that did not pass quality criteria such as those required in this proposed article, which does not mean that they have no value at all. So, concepts such as data relevance, representativeness, freedom of errors and completeness should be better defined or avoided at all. On the other hand, the concept “statistical properties” should be defined. The first part of this provision (“Training, validation and testing data sets shall be relevant, representative, free of errors and complete”)

		seems to introduce an obligation that is potentially unrealistic or at least very difficult to fulfil. Perhaps the specific wording should be softened.
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.	Training, validation and testing data sets shall take into account, whenever possible, to the extent required by (…)	
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.		
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.		
Article 11 Technical documentation		
1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.		
The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national		

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		
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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:		
(a) recording of the period of each use of the system (start date and time and end date and time of each use);		
(b) the reference database against which input data has been checked by the system;		
(c) the input data for which the search has led to a match;		
(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

Article 13 Transparency and provision of information to users		[please see comment to Article 29/2]
1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.		We would like to draw the attention to the fact that, of expressions such as "sufficiently transparent" or "appropriate type of degree of transparency" seems likely to allow those who make them available, a high degree of discretion in (self)evaluating the level of transparency of their own systems.
2. High-risk AI systems shall be accompanied by instructions for use in an	High-risk AI systems shall be accompanied by instructions for field testing and use in an (…)	Specific tasks of system test in operational conditions should be included as mandatory as

appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.		pre-requirement for the use of the high-risk AI systems.
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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;	(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity, including the appropriate statistical properties as referred to in Article 10(3) of the data sets used to train the system, to support operational testing before use, comparing these provided statistical properties with similar statistical properties of data input foreseeable to be found in the operational environment where the system shoud be deployed;	We consider a good practice to perform an assessment of the operational environment where the system will be used. Comparing the statisticals properties of the data sets used to train the system with a data sample of the population where the system should be deployed, allows the user to assume a more protective behaviour in the future use of the system, in particular if the two sets of statisticals properties differ substantially.

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

	(iii) the specific parameters used in testing the system; **(iv) the real conditions of normal use "in the field";**	Considering the list of information specified in the list in Article 13(3), it appears that results generated in the testing phase - for instance, in terms of performance and accuracy - will be sufficient to satisfy the requirements which the rule is intended to cover. However, as experience has shown, these results can be substantially different when the system is tested in a real environment. We would therefore suggest adding to the list a requirement to make available information about the real conditions of normal use of the system and about the parameters used in testing it. Also, the possible ways in which those subjected to the system may be adversely impacted by it could be of some added value.

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		
(iv) its performance as regards the persons or groups of persons on which the system is intended to be used;	(iv) its performance as regards the persons or groups of persons on which the system is intended to be used **and indication on the possible ways in which they may be adversely impacted by it.**	
(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.		
	(vi) esplanatory data recorded during the development of the system to support the field test as referred to in Article XX (new proposed article futher in this document)	We propose to mention technics such as Explainable Artificial Intelligence (XAI), referred in the EC Communication regarding Artificial Intelligence for Europe. The use of these technics should be encouraged given the fact that these can help the debugging and auditing activities previous to the deployment and need for human oversight.
(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		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		
	<new article> Subject: Field Testing 1. Users of high-risk AI systems should, whenever possible, be encouraged to use the data provided by the supplier, as referred to in Article 13, to develop a field test of the system using their own historical data including:	We suggest adding an article to regulate or just suggest the test phase of AI solutions in order to mitigate already identified risks of high-risk AI systems and/or adicionally new risks that should be discovered in the new environement where the system is to be deployed. Comparing the statisticals properties of training data with the statisticals properties of future data inputs

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

	a) the execution of statistical tests on their own historical data to verify that the statistical properties are compatible with those provided by the supplier in accordance with the provisions of Article 10; b) the placing of the high risk AI system running in a controlled environment (sandbox) using their own classified historical data to verify that the performance of the high risk AI system is compatible with the metrics referred to in Article 13 and Article 15. 2. Users of high-risk AI systems should, whenever possible, be encouraged to run a battery of tests on the explanations provided by the system in order to:	should be considered a good pratice. Additionally, we also propose to mention technics such as Explainable Artificial Intelligence (XAI), referred in the EC Communication regarding Artificial Intelligence for Europe. The use of these technics should be encouraged given the fact that these can help the debugging and auditing activities previous to the deployment and need for human oversight.

	a) test the meaning of the explanations and their level of significance for different test groups; b) compare the explanations obtained with those provided by the provider in accordance with Article 13.	
Article 14 Human oversight		W recommend defining the concept of "effective human oversight" and the specific results this article intends to seek. In our view, "human oversight" differs depending on the deployment scenario and the nature of the related risks. Consequently, we recommend that the proposed Regulation requires deployers to implement sufficient, qualified human oversight as is appropriate to the deployment scenario at issue. It is also important to bear in mind that for the "human oversight" to be meaningful and

		successful it is necessary to ensure that the humans performing the oversight are trained and equipped appropriately in accordance with the instructions of use and other information provided by the supplier. Additionally, the oversight should be tied to the intended use of the AI system and accountability mechanisms should be created to assess the effectiveness of the human overseer. [Please see comment to article 29/3]
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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		
	(c) identified by the user, defining non-technical organisational measures to ensure robust human supervision, consisting of at least training for decision-makers, registration requirements, and clear *ex-post* review processes.	In our opinion, it is still not sufficiently clear whether the human supervision measures in Article 14 apply to the user or to someone independent from the user, or even whether "user" refers to the organisation using the AI system as a whole or to a specific individual who is responsible for a particular decision. In fact, we believe that supervision is necessary for all actions related to the development, implementation and use of AI systems, to ensure

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		that fundamental rights are protected in the best possible way at every stage. This will include, of course, human supervision of the process, but also regular and independent human supervision of the very people who participate in it and who are ultimately responsible for making the final decision, informed by the outputs produced by the system. It is not enough, therefore, to know whether supervisors are properly aware of the possibility of bias, but it must also be possible to demonstrate, transparently and effectively, that the actual decisions were not taken on the basis of excessive confidence in the outputs produced by the system. We, therefore, believe it is advisable to add a third category to Article 14(3) that adequately recognises the need for users to put in place organisational measures to ensure

		robust human supervision, consisting of at least: training for decision-makers, registration requirements, and clear ex-post review processes.
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 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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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.		
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.	~~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.~~ OR 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	In our opinion, reliance on human supervision as a sufficient safeguard should only be considered when it is possible to prove that the use of intrusive systems is necessary and proportionate in a democratic society, preventing it from functioning to legitimize the use of technologies that should not be used in light of their potential to violate fundamental rights. We would therefore reiterate that human supervision cannot act as a panacea for the (very serious) problems that the use of certain systems can give rise to, and consequently cannot be

	of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons, **based on a separate/independent assessment by each of them.**	used to validate and – by that way, legitimize – that system or its use in a given context. In order to ensure any useful effect to this provision, the verification carried out by at least "two natural persons" **should be based on a separate assessment by each of them.** For example, by requiring that one is 'in the field' to identify, or 'spot', the individual in question from a different perspective, rather than reducing this requirement to a verification made by two people side-by-side looking at the same screen.
Article 15 Accuracy, robustness and cybersecurity		
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		According to the proposed Regulation the "high-risk AI systems shall be designed and developed in such a way that the achieve, in the

appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.		light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle." However, it is not defined what it means "an appropriate level of accuracy, robustness and cybersecurity", is 90% accuracy appropriate or 70%? And does the appropriate level changes depend on the context? If it is a critical infrastructure or a system used in a factory? We strongly recommend the development of best practices and standards do define these and other concepts.
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.		We recommend reviewing the first paragraph of this article, taking into account the definition of "intended purpose" set in article 3, number 12 of the proposed Regulation. Please note that it is not possible to ensure that AI systems are 100% resilient to errors, faults, or inconsistencies. The uncertainty is part of the AI system. We also suggest adding the importance of quantifying this uncertainty, given its high impact on other topics addressed in this proposal, such as the risk of AI systems.

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.	The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans, **such as the inclusion of mechanisms that prohibit some unexpected system behaviours, including preventing the system from operating, if inputs or outputs fall outside a predefined "safe" range.**	To help shape the standardisation process appropriately, further clarification and indicative examples could be added in article 15.
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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

Article 19 Conformity assessment		
1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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:		
(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		The article foresee that importers and distributors should not place on the market or make the system available, and the difficulty is in determining whether an importer or distributor has established capabilities to recognize non-compliance for an AI system.

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		
Article 27 Obligations of distributors		The article foresee that importers and distributors should not place on the market or make the system available, and the difficulty is in determining whether an importer or distributor has established capabilities to recognize non-compliance for an AI system.
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.		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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,		This standard establishes characteristics and competences that should be of the exclusive responsibility of those who develop AI systems, considering that this obligation will be, once again, difficult to observe.

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.		
Article 28 Obligations of distributors, importers, users or any other third-party		It refers to "other third parties", but who are they are: users, distributors, suppliers?
1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:		
(a) they place on the market or put into service a high-risk AI system under their name or trademark;		

(b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service;		The topic is unclear about the intended purpose change. Perhaps the definition is too broad and therefore brings uncertainties
(c) they make a substantial modification to the high-risk AI system.		The article is unclear about the "substantial change". Perhaps the definition is too broad and therefore brings uncertainties
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		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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.		With regard to the problem of "explainability", Article 13 specifies that "high risk" AI systems must be developed and designed to be sufficiently transparent to ensure the user's ability to interpret and use the results of the system. **However, it does not include an explicit obligation on the user to communicate such information to the persons targeted by the decision supported by Artificial Intelligence** (the only transparency obligation towards these persons is stipulated in Article 52, but limited to the duty to inform them

		of the fact that an Artificial Intelligence system is being used). **The Proposal does not, as such, include obligations on users of Artificial Intelligence to explain or justify the decisions they take to those affected by them, let alone a corresponding right of these individuals to demand i**t. While they may be protected by the general right to a reasoned decision under Article 41(2c) of the Charter to fill this gap, the specific challenges its application raises when public bodies rely on these systems in their decision-making would justify the inclusion of additional safeguards**. Therefore, to avoid any doubt regarding the applicability of this right in the context of Artificial Intelligence it should be made clear in the text of the Regulation and the references used to assess compliance with this right should be duly included in the text of the**

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

		Proposal itself. As these aspects are central to the review, by the person targeted by decisions supported by these technologies, it would be important not to leave their densification to supervening disputes.
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.	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. **When using AI systems in their decision-making processes, public authorities or others acting on their behalf shall inform the persons affected by them whether or not other available information was used and if alternative results were considered.**	Concerning the issue of "algorithmic bias", it is important to avoid that decisive importance is given to the result suggested by an algorithm while neglecting other available information, in which case the public authority can make the mistake of basing a decision on the argument "it is so because the machine determined it". To this effect, Article 14 of the Proposal requires that human supervision must be ensured in order to allow the person assigned this task to correctly

		interpret the results and be aware of the potential bias. While welcoming the explicit consideration of such matter, we believe it would be important to combat it more effectively by requiring additional safeguards, for example by obligating the public authority that relies on AI systems for its decision-making to report whether or not it has used other available information or considered alternative results in issuing its decision.
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.		
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 TECHNIQUES AND APPROACHES** **referred to in Article 3, point 1**		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;		
(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;		
(c) Statistical approaches, Bayesian estimation, search and optimization methods.		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

ANNEX II **LIST OF UNION HARMONISATION LEGISLATION** **Section A – List of Union harmonisation legislation based on the New Legislative Framework**		
1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];		
2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009		

on the safety of toys (OJ L 170, 30.6.2009, p. 1);		
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);		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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);		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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).		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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);		
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.		
ANNEX III **HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)**		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:		We highlight the definition of the 'intended purpose' that "means the use for which an AI system is intended by the provider, including the specific context and conditions of use". This annex ignores totally the "conditions of use", and we consider that this should be mentioned whenever possible to avoid grey zones in any of the points listed.
1. Biometric identification and categorisation of natural persons:		
(a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

2. Management and operation of critical infrastructure:		
(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.		
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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

(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.		
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:		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		
(e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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 formats in order to identify unknown patterns or discover hidden relationships in the data.		
	(h) AI systems which do not explicitly rely on personal data used by law enforcement	In our opinion, the list included in point 6 of Annex III is mostly focused on systems that have natural

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

	authorities to determine law enforcement resource deployment or policing prioritisation	persons as their subjects and by doing so seems to fail to identify optimisation systems that use geospatial data to determine law enforcement resource deployment as high-risk systems (otherwise known as 'predictive policing,' or 'crime hotspot analytics systems'). Despite not relying on personal data of natural persons, the fundamental rights implications of these systems are important because they are used to determine who can be subject to increased police intervention (based on geographical location), how these interventions occur, and with what frequency. Used without due safeguards, these systems may lead to over-surveillance of specific geographical locations and further aggravate existing problems with discrimination arising from racial and socio-economic biases in some existing policing datasets.

		As such, including law enforcement AI systems that do not explicitly use personal data (e.g. crime hotspot analysis based on geospatial data) in the list of high-risk systems could be a way to tackle this issue.
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;		
(b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular		

immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;		
(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;		
(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		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

to the eligibility of the natural persons applying for a status.		
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~~ **or** interpreting facts and the law ~~and~~ **or** in applying the law to a concrete set of facts;	The wording used in point 8 of Annex III needs to be clarified as it leaves some room for legal uncertainty, as it is clearly pointed out in document 11368/21: *«'researching **and** interpreting facts and the law **and** […] applying the law'*: the wording seems to indicate cumulative criteria. An AI system that only assists the judicial authority 'in researching facts' but not in 'interpreting' them or 'in applying the law' would thus not be considered high risk.» In order to avoid this, it should be made clear that the use of any AI system to "assist" the judicial authority in any of the indicated roles – regardless

		of whether its purpose is research, interpretation or application of the law – should be subject to the same guarantees, since these are essential, as they protect fundamental rights, avoid the "black box" effect and the problem of algorithmic bias. This would, of course, be in line with the wording in Recital 40, which excludes from the classification as "high-risk" « (…) AI systems intended for purely ancillary administrative activities that do not affect the actual administration of justice in individual cases, such as anonymisation or pseudonymisation of judicial decisions, documents or data, communication between personnel, administrative tasks or allocation of resources'.»
	9. Healthcare a) AI systems intended to support the diagnosis; b) AI systems intended to monitor patient's vital signs; **AI systems intended to assist the**	In our opinion, it would probably be important to consider the insertion of a specific mention to the penitentiary sector, which does not seem to be sufficiently taken into account in the text, considering that some decisions related to the execution of sentences are not taken by judicial

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

	competent authorities in decisions concerning the execution of sentences. c) AI systems intended to automate the generation of treatments plans.	authorities and would therefore not fall under the 'administration of justice'.
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:		

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

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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;		

(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);		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

(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;		

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use ~~strikethrough~~ to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

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**