Meta's AI Act Position – 4 Column Document

Meta is in favour of regulation that is risk-based and technology neutral. This approach regulates the uses of the technology, rather than the technology itself. As a result, said approach ensures that the regulation is applied proportionately, introducing requirements to ensure protections in high-stakes settings, whilst avoiding hindering innovation in lower-risk areas. The original draft of the AI Act is, for the most part, underpinned by these characteristics, which we welcome.

The following principles would help to ensure that the final text retains that same focus, avoids duplication of other regulations, and is responsive to recent and future developments in AI technology.

Principle 1: The AI Act should maintain the risk-based approach and not create an additional regime for foundation models (Art. 28b – 4 Column Document 379d)

Recommended Approach: Maintain the technology-neutral, risk-based approach of the AI Act.

Foundation models are not inherently risky. As with other AI systems, the risks arise dependent on the context in which they are deployed. It is unnecessary, therefore, to introduce requirements for providers of foundation models. Our recommendation is to retain the risk-based, technology-neutral approach of the EU AI Act and reject these additions.

Compromise position 1: Providers who make their foundation models available through open source or similarly permissive licences that:
> **(i) provide open access to models;**
> **(ii) further the goal of fostering collaboration and innovation; and**
> **(iii) permit downstream users to use, reproduce, distribute, copy, create derivative works of, and make modifications to the foundation model**

should be exempt from requirements for providers of foundation models.

The AI Act should incentivise approaches that support the EU's goals for fostering AI innovation in Europe. In its Parliament version the AI Act includes an exemption for open source AI systems, in recognition of the critical role that open source development plays in driving innovation and delivering economic benefits from new technologies. In the coming years, access to foundation models will play a

similarly crucial role in driving AI research, development, innovation and adoption. It is essential, therefore, that the AI Act facilitates widespread access to, and innovation in foundation models.

To do so, providers of foundation models should be granted an exemption from the requirements of the Act whenever they decide to make their models available under open source or similarly permissive licences. An approach of this type, which can be described as *open innovation,* would not only allow European researchers, developers, and citizens to benefit from advances in foundation models, but also contribute to the creation of higher-performing, safer, and more secure foundation models as a broad community is able to test, scrutinise and improve openly available models.

Please note that Principle #2 below applies independently and regardless of the current compromise.

Compromise position 2: Providers of foundation models should be subjected to a tailored obligation regime.
If the decision is made to introduce some requirements for all foundation models, by virtue of their nature alone, **a distinction of such requirements must be made between providers**
- **who make their models available** in an open and transparent way, such as **under open source or similarly permissive licences that:**
  (i) provide open access to models;
  (ii) further the goal of fostering collaboration and innovation; and
  (iii) permit downstream users to use, reproduce, distribute, copy, create derivative works of, and make modifications to the foundation model.
- **and those that take a closed approach**.

In addition, improvements must be made to the current text to ensure that requirements are technically feasible and tailored to their purpose. Requirements applicable to all foundation models might focus on transparency, data governance, technical documentation, and risk assessment, in line with industry best practices, while providers of closed models may be expected to meet additional requirements, so as to provide additional assurance and oversight of those models. These additional measures need not apply to open models, as these models are at the disposal of more downstream developers, who can in turn scrutinise the software, identify and fix potential issues and therefore improve performance, safety, and security.

In this regard, we recommend a tiered regime in which Art.28b applies only when the foundation model is released under a closed system. If the foundation model is released under open source or similarly permissive licences, on the other hand, we propose a new Art.

28c to be included in the AI Act, amending Parliament's proposed 28b to better adapt to the nature of open models and to continue to maintain that risk-based approach that is core to the Act.

Please note that Principle #2 below applies independently and regardless of the current compromise.

Principle 2: The AI Act is not the right place to regulate copyright, which is addressed by existing EU regulations. (Art. 28b, paragraph 4b and c – 4 Column Document 379d)

Regardless of the treatment of foundation models, it must be clarified that copyright provisions (in this case, Art. 28b, paragraphs 4b and 4c) should not be addressed in the AI Act. The rules introduced in the AI Act should build upon existing legislation, not duplicate it or clash with it. The matter of copyright obligations is already covered by Directive (EU) 2019/790 of the European Parliament and of the Council. The AI Act should, thus, defer to it. 4b and 4c should be removed from the text. In particular:

- **28b(4)(b):** The requirement to provide safeguards against the generation of content in breach of Union law is vague, overbroad, and at odds with fundamental EU principles of proportionality and legal certainty. Ensuring that adequate safeguards are in place should be the responsibility of the user of the generative product, since they are the ones that are most familiar with the functionality of the system, the audience it is used by, and its functionalities.
- **28b(4)(c):** As the EU Directive on Copyright in the DSM (articles 3 and 4) already provides control to rights holders over the use of their protected works for the purposes of training AI, the focus should be to encourage and facilitate industry collaboration e.g. for the development of workable standards to ensure the effective control of rights. The proposal concerning copyright law in Art. 28b(4) does not go to the specified objectives of the AI Act. It is broad and unworkable, and, moreover, there is already an extensive and robust EU legal framework in place ensuring IP protection.

Principle 3: The AI Act should avoid duplicating existing and planned EU regulations.

As the AI Act has progressed, its scope has expanded beyond the risk-based, technology-neutral proposal put forward by the Commission. In some cases, this has resulted in provisions which are duplicative of other EU laws. This will lead to confusion and potential conflict of regulatory requirements.

Specifically, the European Parliament has proposed amendments to add new types of systems to Annex III, which are already regulated in other regulatory instruments. These include:

- **AI systems intended to be used for influencing the outcome of an election or the voting behavior** (**Annex III paragraph 8, point aa – 4 Column Document 837a):** Given that back-end systems are excluded, it appears as though this amendment is aimed at systems, or their outputs, that natural persons would be exposed to. This could include political advertising, non-political content relating to elections such as 'get out and vote!' campaigns, or content relating to causes such as climate change, social justice, or reproductive rights that are not party political, but which often feature in political discourse and can shape voting behaviour.
  The Digital Services Act (DSA), which is a content regulation and which includes the specific obligation for Very Large Online Platforms (VLOPs) to manage systemic risks relating to "any actual or foreseeable negative effects on civic discourse and electoral processes" is the appropriate instrument for addressing content concerns. The AI Act should not duplicate that regulation.
- **Recommender systems used by VLOPs under the DSA (Annex III, paragraph 8, point ab – 4 Column Document 837b):** AI systems intended to be used by social media platforms that have been designated as very large online platforms (VLOPs) under the Digital Services Act (DSA). Similarly, Annex III(8)(ab) targets recommender systems, which are already regulated in the DSA and do not require separate measures.
  - First of all, the original list of Annex III includes areas such as law enforcement, employment, education, asylum, critical infrastructure and access to public services. Social media recommender systems are not operated in these potentially sensitive areas, where the effect could be of legal nature or similarly significant.
  - Secondly, under the DSA, providers of Recommender Systems are subjected to a wide range of obligations, mostly around transparency, risk assessment and mitigation. When drafting AI regulation, regulators should build upon existing legislation that already impacts AI, without creating tension with existing obligations.

Similarly, The Parliament's text proposes labeling AI generated content as a solution to combat the risk of misinformation from AI generated deep fakes.

- **Labeling (Art. 52, paragraph 3– 4 Column Document 515):** An emerging concern relates to the risk of misinformation from AI generated deep fakes. The Parliament's text proposes labeling this type of content as a solution. However, it is not clear that labeling is the best approach to address this risk. AI technologies are evolving rapidly, with new techniques and products emerging all the time. Rather than being prescriptive about how companies should address emerging concerns, the AI Act must be flexible enough to allow for evolving best practices to be adopted, as emerging risks become better understood, and

standards are established. This could be further explored in the Code of Conduct on Disinformation and/or via peer collaboration and standard-setting bodies. For example, this could be done by developing a framework that enables users to distinguish audio or visual content generated by AI that would otherwise be indistinguishable from reality. Moreover, the DSA already places a requirement under Article 35 for platforms to mitigate risks in this area, and it's important that the AI act does not create conflicting or duplicative requirements.

Outline

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
Formula					
1	2021/0106 (COD)	2021/0106 (COD)	2021/0106 (COD)		
Proposal Title					
2	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	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	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		
Formula					

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3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Article 2					
109	Article 2 Scope	Article 2 Scope	Article 2 Scope		
Article 2(5e) new					
125h		This Regulation shall not apply to AI components provided under free and open-source licences except to the extent they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV. This		**Parliament's version with amendments** This Regulation shall not apply to AI components provided under free and open-source *or similarly permissive licences that: (i) provide open access to models; (ii) further the goal of fostering collaboration and innovation; and (iii) permit downstream users to use, reproduce, distribute,*	We welcome the exemption introduced in article 2 (5e), which carves out components from the requirements of the AI Act. In fact, we believe this exemption supports an adequate balance between prevention of risk and encouragement of innovation. On the one hand open source drives innovation because it enables many more developers to build with new technology; on the other it strengthens safety and security because it allows more people to

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		exemption shall not apply to foundation models as defined in Art 3.		***copy, create derivative works of, and make modifications to the model, whether provided by a commercial or non-commercial entity,*** except to the extent they are placed on the market or put into service by a provider as part of a high-risk AI system or of an AI system that falls under Title II or IV. ~~This exemption shall not apply to foundation models as defined in Art 3.~~	scrutinize the software to identify and fix potential issues.

However, excluding foundation models from this exemption, and even more subjecting them to a very specific set of obligations under article 28(b), risks jeopardizing this important objective. Subjecting open source foundation systems to the obligations specified under Art. 28(b) would be a disincentive for providers of foundation models from making those models available on a open source basis, undermining the established benefits which the open source model brings in terms of building trust, leveraging the expertise of thousands of contributors, benefiting competition and spurring responsible innovation by making such models available to third parties that might otherwise not have access to the technology or the means to develop such systems themselves.

Secondly, one of the principles underpinning the |

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					AI Act is its risk-based approach, which entails a proportionality of the regulatory requirements. This is confirmed by its Explanatory Memorandum at paragraph 2.3, which specifies that "for high risk AI systems, the requirements(…)are strictly necessary to mitigate the risks to fundamental rights and safety posed by AI". Based on this principle, an AI system should be subjected to the requirements of the AI Act solely when it meets that high-risk threshold. Subjecting foundation models to specific provisions, merely by virtue of their being "foundation models" contradicts the very risk-based spirit of the Act.
Article 3					
126	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions		
Article 3, first paragraph					
127					

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	For the purpose of this Regulation, the following definitions apply:	For the purpose of this Regulation, the following definitions apply:	For the purpose of this Regulation, the following definitions apply:		
Article 3, first paragraph, point (1)					
128	(1) 'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;	(1) 'artificial intelligence system' (AI system) means ~~software~~ *__a machine-based system__* 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__*designed to operate with varying levels of autonomy and that can, for explicit or implicit*__ objectives, generate outputs such as ~~content,~~ predictions, recommendations, or decisions*__, that influence physical or virtual environments__* ~~influencing the environments they interact with~~;	(1) 'artificial intelligence system' (AI system) means ~~software~~**a system** that is ~~developed with one or more of the techniques and approaches listed in Annex I and can,~~ **for**~~designed to~~ **operate with elements of autonomy and that, based on machine and/or human-provided data and inputs, infers how to achieve** a given set of ~~human-defined objectives,~~ **generate**objectives **using machine learning and/or logic- and knowledge based approaches, and produces system-generated** outputs such as	**Parliament's version** (1) 'artificial intelligence system' (AI system) means ~~software~~*__a machine-based system__* 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__*designed to operate with varying levels of autonomy and that can, for explicit or implicit*__ objectives, generate outputs such as ~~content,~~ predictions, recommendations, or decisions*__, that influence physical or virtual environments__* ~~influencing the environments they interact with~~;	**The Parliament's version** of the text is adopting the right approach. In fact, it moves away with an overly broad definition that would encompass virtually all kinds of software, and endorses one that mirrors the internationally-recognized one, put forth by the Expert Group on AI at the OECD. Just like the latter, the Parliament's definition of AI system revolves around software that a) is machine based and b) is able to learn over time. In doing so, it captures the distinction between complex AI systems and general logic-based algorithms, consequently making sure the Act targets the novel risks that AI systems uniquely present. It also avoids an overly broad scope that may impose regulatory burdens on technologies that do not present the same challenges that the Act intends to tackle.

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			content **(generative AI systems)**, predictions, recommendations~~,~~ or decisions**,** influencing the environments ~~they interact with~~**with which the AI system interacts**;		

Article 3, first paragraph, point (1c new)					
128e		*(1c) 'foundation model' means an AI system model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;*		**Scenario 1** ~~*(1c) 'foundation model' means an AI system model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;*~~	**Scenario 1** Whether or not this definition should be included here, and in what form, depends on the decision of whether Foundation Models should be regulated at all or not in the Act. **The original draft by the Commission**, is the most desirable outcome: foundation models are not specifically included in the Act. In fact, the Parliament's choice to include a specific provision on them would undermine the risk-based approach that underpins the Act and treat foundation models as high risk AI systems without that being the actual case.

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				Scenario 2: *(1c)* ***'foundation model' means an AI system model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks;***	**Scenario 2:** In the event that the provision is maintained **in the Parliament's version**, it is recommended for the definition to be amended to refer to "AI model" rather than "AI System model". That is because foundation models are not AI Systems, and this description does not adequately describe their nature, operation or functioning.
128c			(1b) 'general purpose AI system' means an AI system that - irrespective of how it is placed on the market or put into service, including as open source software - is intended by the provider to perform generally applicable functions such as image and speech recognition, audio and video generation, pattern detection, question answering, translation and		

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			others; a general purpose AI system may be used in a plurality of contexts and be integrated in a plurality of other AI systems;		
Article 3, first paragraph, point (1d new)					
128f	N/A	*(1d) 'general purpose AI system' means an AI system that can be used in and adapted to a wide range of applications for which it was not intentionally and specifically designed;*		**Commission's version** ~~*(1d) 'general purpose AI system' means an AI system that can be used in and adapted to a wide range of applications for which it was not intentionally and specifically designed;*~~	It is recommended to maintain the **Commission's position**, and thus to strike the definition of the Act. The Parliament introduces this definition without accompanying it with any real obligations, therefore this definition does not serve any real purpose and may generate confusion or redundancy.
Article 3, first paragraph, point (1e new)					
128g	N/A	*(1e) 'large training runs' means the production process of a powerful AI model that require computing resources above a very high threshold;*	N/A	**Commission + Council's versions.** ~~*(1e) 'large training runs' means the production process of a powerful AI model that require computing resources above a very high threshold;*~~	**The Commission version, adopted also by the Council,** is preferable here. It is recommended for this definition to be struck out of the Act. There is no real obligation attached to large training runs except the one introduced by the Parliament in article 56b upon the AI Office to issue guidelines that would qualify training a

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					"foundation model" as a "large training run" and document known instances of such large training runs. However, it is unclear what such qualification would entail, or the objective this qualification would pursue. For these reasons, it is recommended for this concept to be removed both here and under article 56b (see below).
Article 3, first paragraph, point (33a new)					

| 160a | | *(33a)* *'biometric-based data' means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person;* | | Commission + Council's versions. ~~(33a)~~ ~~'biometric-based data' means data resulting from specific technical processing relating to physical, physiological or behavioural signals of a natural person;~~ | **The Commission version, adopted also by the Council,** is preferable here**.** In this definitory expansion, it is particularly concerning that Parliament has chosen to rely on a newly introduced definition - that of **biometric-based data** - which could potentially encompass a large subset, if not all, of the interaction that a user has with technology. To provide just a few examples, whenever people interact with a computer, the computer uses data such as movements, voice, key strikes, hand gestures, and more in order to perform specific actions. When someone moves a mouse cursor over a folder and double clicks, the computer must use hand movements in order to infer whether the person intends to highlight or open the folder. Similarly, when someone invokes a voice assistant to call a relative, the computer must infer the intent to place a call. Moreover, and equally importantly, the new definition of biometrics-based data appears superfluous and potentially counterproductive. The EU AI Act already includes a definition of biometric data, which aligns |

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					with GDPR. This alignment is more than welcome, to maintain consistency and uniformity across legislation, and to avoid duplication or conflicting rules. Biometric data is considered as a "special category of data" under GDPR only if used for the sole purpose of uniquely identifying a person, and **only in that case,** due to its unique identifying properties, receives additional specific obligations from the regulator. The same is not true for the newly defined " biometric-based data". As the report itself confirms, this newly coined category *"may not allow or confirm the unique identification of a natural person",* and therefore never share the particularities that make biometric data deserving of particular attention. Expanding transparency and explainability requirements to any processing of data that may not even identify the individual rejects the hallmark of personal data definition and stretches out requirements to areas that will not pose privacy concerns.

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					Finally, the EU AI Act should not establish and define new forms of personal data processing activities. If anything, these should remain the competence of GDPR. For all these reasons, and to avoid unnecessary overscoping in contrast with the high risk basis that underpins the act, striking this definition and sticking with the Commission's proposal, also endorsed by the Council, is advisable.
Article 3, first paragraph, point (33b new)					
160b		*(33b) 'biometric identification' means the automated recognition of physical, physiological, behavioural, and psychological human features for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored biometric data of individuals*		**Commission + Council's versions.** *(33b) 'biometric identification' means the automated recognition of physical, physiological, behavioural, and psychological human features for the purpose of establishing an individual's identity by comparing biometric data of that individual to stored*	**The Commission version, adopted also by the Council,** is the right approach**.** Just like it happens with the above definition of biometric-based data, the Parliament is attempting to introduce a new category of data processing that does not align with the existing legislatory framework and goes beyond what is the mandate of the AI Act. The GDPR already contains a definition of biometric data, which rises to the status of "Special Category of

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		in a database (one-to-many identification);		*biometric data of individuals in a database (one-to-many identification);*	Data" when used for the purpose of uniquely identifying a natural person. The GDPR does not determine or differentiate how that identification is done. In this case, the Parliament is introducing a processing of biometric data, which would be used for identification purposes, but carried out in a specific manner - that is by comparing certain data with data from the same individual that was previously stored. This definition appears redundant: GDPR already speaks about biometric data that is processed for identification, and that definition and provision is generic enough that would encompass this case as well. There is no additional need to introduce a variation of the definition of biometric data. Additionally, considering the risk-based approach of the Act, it does not seem reasonable to exclude from the list of High Risk uses cases the case of biometric data used for identification purposes. This is because GDPR, instead, treats this

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					particular case as one deserving special treatment. The Regulator should pursue an approach that **complements** and **aligns** with existing legislation, but not conflicting with it. Maintaining the Commission and Council's version, and thus deferring to GDPR, is the correct approach.
Article 3, first paragraph, point (33c new)					
160c		*(33c) 'biometric verification' means the automated verification of the identity of natural persons by comparing biometric data of an individual to previously provided biometric data (one-to-one verification, including authentication):*		**Commission + Council's versions** *(33c) 'biometric verification' means the automated verification of the identity of natural persons by comparing biometric data of an individual to previously provided biometric data (one-to-one verification, including authentication):*	**The Commission version, adopted also by the Council,** is preferable here**.** Similarly as above, this definition appears redundant and out of place. The definition should remain consistent with the approach taken by GDPR, which is and should continue to be the piece of legislation governing the definition of biometric data and its treatment.
Article 3, first paragraph, point (34)					
161	(34) 'emotion recognition system' means an AI system for the	(34) 'emotion recognition system' means an AI system for the purpose of	(34) 'emotion recognition system' means an AI system for the purpose of	**Maintain Commission Text:** (34) 'emotion recognition system'	**The original proposal by the Commission continues to appear like the right**

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	purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;	identifying or inferring emotions, *thoughts, states of mind* or intentions of ~~natural persons~~*individuals or groups* on the basis of their biometric *and biometric-based* data;	identifying or inferring **psychological states,** emotions or intentions of natural persons on the basis of their biometric data;	means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;	**approach**. Expanding the definition of emotion recognition systems to include thoughts and states of mind (Parliament's version), or psychological states (Council's version) is problematic because the entire experience of human cognition consists of thoughts and states of mind. A broad definition of emotion recognition system, furthermore when combined with the proposed definition of **biometric-based data**, means that AI systems with little to no level of risk, including those that provide text auto-complete, autocorrect, or even spell-check would be covered because the AI is using key strikes or movement or a combination of letters typed in order to determine the thoughts of the user, in this case the intended words. The obligations attached to emotion recognition are those of article 52, namely user of "emotion recognition systems" are required to "inform of the operation of the system the natural persons exposed thereto" in accordance with Article 52. Requiring similar constant disclosure to be delivered to the user would be

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					unnecessary in most of these circumstances - again, the user is certainly aware that by moving the mouse in a certain direction and clicking, they are telling the computer to perform a specific action. Even more so, it would be overburdening for the user, who would be inundated by disclosure to the point that they would absolutely lose relevance. For these reasons, returning to the more narrowly scoped version of the Commission is the sensible choice.
Article 3, first paragraph, point (35)					
162	(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;	(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~~ _or inferring their characteristics and_	(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;	**Maintain Commission Text** (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;	**The Commission text is the most appropriate one here.** This is the proposal that most aligns with the definition of biometric data that is provided in GDPR and that, as mentioned above, should be the benchmark of all other definitions. The Parliament's definition departs from the GDPR one because it includes the idea of "inferences"

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		attributes on the basis of their biometric or biometric-based data, or which can be inferred from such data;			
Article 3, first paragraph, point 45 (new)					
NEW	N/A	N/A	N/A	(*) Harmful Subliminal Technique: means a measure whose existence and operation is entirely imperceptible by those on whom it is used, and which has the sole purpose and direct effect to induce actions leading to that person's physical or psychological harm. **OR** 'subliminal techniques' means techniques that use sensorial stimuli such as images, text, or sounds, that are below the threshold of conscious human perception.	Currently, none of the three drafts include any definition of "Subliminal Technique". However, these practices are subject to the strictest provision in the Act, namely Article 5, which prohibits them in their entirety. Prohibiting certain uses of AI is the most blunt and drastic tool available to the Regulator, and the violation of this provision would lead to severe penalties. Consequently, it is imperative that the scope of the prohibition be circumscribed and specifically scoped to ensure this applies indeed to the most dangerous and threatening uses of AI. Lacking a precise definition of what these "subliminal techniques" are, the prohibition risks targeting more applications than

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					intended and, consequently, curbing innovation and deterring investments in potentially beneficial technology. Particularly, the suggested definition is in line with the interpretation that has been given by VP's Vestager in her remarks at the press conference on AI: *"(At the top of the pyramid, we find those - limited - uses of AI that we prohibit altogether because we simply consider them unacceptable. It is AI systems that use subliminal techniques to cause physical or psychological harm to someone. For example, in the case of a toy that uses voice assistance to manipulate a child into doing something dangerous. Such uses have no place in Europe. We therefore propose to ban them")*. In fact, it clearly and explicitly references the following characteristics: a) imperceptibility by the subject; b) objective and effect to induce that subject to conduct unwanted actions; c) those actions need to be harmful. We believe introducing these

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					specifications would help ensure the strictest provision of the Act has the intended effect, which is to prevent only the riskiest uses of AI, and that the risk-based approach - which underpins the Act - is indeed maintained.
TITLE II					
178	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES		
Article 5					
179	Article 5	Article 5	Article 5		
Article 5(1)					
180	1. The following artificial intelligence practices shall be prohibited:	1. The following artificial intelligence practices shall be prohibited:	1. The following artificial intelligence practices shall be prohibited:		
Article 5(1), point (a), first subparagraph					
181	(a) the placing on the market, putting into	(a) the placing on the market, putting into service or use	(a) the placing on the market, putting into service or use	**Council text with amendments** (a) the placing on the market, putting	**The Council** has significantly improved the Commission's version of the

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	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;	of an AI system that deploys subliminal techniques beyond a person's consciousness ~~in order to~~ *or purposefully manipulative or deceptive techniques, with the objective to or the effect of* materially ~~distort~~*distorting* a person's *or a group of persons'* behaviour *by appreciably impairing the person's ability to make an informed decision, thereby causing the person to take a decision that that person would not have otherwise taken* in a manner that causes or is likely to cause that person ~~or~~ another person ~~physical or psychological~~*or group of persons significant* harm;	of an AI system that deploys subliminal techniques beyond a person's consciousness ~~in order to~~ **with the objective to or the effect of** materially ~~distort~~**distorting** a person's behaviour in a manner that causes or is **reasonably** likely to cause that person or another person physical or psychological harm;	into service or use of an AI system that deploys **harmful** subliminal techniques beyond a person's consciousness ~~in order to~~ **with the objective to or the effect of** materially ~~distort~~**distorting** a person's behaviour in a manner that causes or is **reasonably** likely to cause that person or another person physical or psychological harm;	text. In particular, it has added two important criteria that the techniques at issue need to meet for them to be considered subliminal: 1) The techniques at issue need to have the objective to change the behaviour of the person on whom they are applied; 2) The harm needs to be a direct consequence of the subliminal technique used, and the harm caused needs to be foreseeable, material and either physical or psychological. Article 5 is the strictest provision in the Act, as it prohibits certain uses of the technology altogether. For this reason, it must be clear and accurately scoped, to avoid curbing innovation and preventing beneficial uses of AI. For this reason, and to avoid overscoping, **the Council version** could be further improved by adding an additional criterion: the subliminal techniques referenced must indeed be **harmful.** This is to avoid the effect of discouraging investments and developments in less risky areas, or potentially

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
					preventing beneficial economic activities, which could end up being unintentionally encapsulated in this unclear prohibition. An example of this would be personalised advertising, which as some have suggested may be captured under this provision.
Article 5(1), point (a)					
181a		_**The prohibition of AI system that deploys subliminal techniques referred to in the first sub-paragraph shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian;**_		**Parliament's version** _**The prohibition of AI system that deploys subliminal techniques referred to in the first sub-paragraph shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian;**_	**The Parliament text is following the right approach** by introducing a carve out from the prohibition wherever there's a therapeutic use and a specific informed consent by the user. Because the intent of Art. 5 is to prohibit the use of the riskiest/most harmful uses of AI, it is a sensible choice to exclude from said prohibition the cases where the techniques have the potential to be beneficial, such as in therapeutic context, and when the user is made aware and has expressed their consent to said practice.
Article 5(1), point (b)					

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
182	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a *person or a* specific group of persons*, including characteristics of such person's or a such group's known or predicted personality traits or social or economic situation* ~~due to their~~ age, physical or mental ~~disability, in order to~~ *ability with the objective or to the effect of* materially ~~distort~~*distorting* the behaviour of *that person or* a person pertaining to that group in a manner that causes or is likely to cause that person or another person ~~physical or psychological~~*significant* harm;	(b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, ~~physical or mental disability, in~~ ~~order to~~**disability or a specific social or economic situation, with the objective to or the effect of** materially ~~distort~~**distorting** the behaviour of a person pertaining to that group in a manner that causes or is **reasonably** likely to cause that person or another person physical or psychological harm;	**Council's version** (b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, ~~physical or mental disability, in~~ ~~order to~~**disability or a specific social or economic situation, with the objective to or the effect of** materially ~~distort~~**distorting** the behaviour of a person pertaining to that group in a manner that causes or is **reasonably** likely to cause that person or another person physical or psychological harm;	The same criteria of intent, foreseeability and material harm should apply to AI systems aiming at exploiting the vulnerabilities of a group, in order to ensure predictability and legal certainty of the provisions. For this reason, **the Council's version** is the one that achieves this purpose and thus the best option.
Article 5(1), point (ba new)					
182a		*(ba) the placing*		**Maintain Commission's**	

[1]'Speech by Executive Vice-President Vestager at the press conference presenting a European approach to Artificial Intelligence (April 21, 2021).
https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_1866

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		on the market, putting into service or use of biometric categorisation systems that categorise natural persons according to sensitive or protected attributes or characteristics or based on the inference of those attributes or characteristics. This prohibition shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.		**version** ~~*(ba) the placing on the market, putting into service or use of biometric categorisation systems that categorise natural persons according to sensitive or protected attributes or characteristics or based on the inference of those attributes or characteristics. This prohibition shall not apply to AI systems intended to be used for approved therapeutical purposes on the basis of specific informed consent of the individuals that are exposed to them or, where applicable, of their legal guardian.*~~ **Move this to Annex III**	classified as sensitive data to the extent that it is used for identification purposes. This is to prevent negative outcomes such as unlawful discrimination. However, when it comes to biometric categorisation the choice of the Parliament in the AI Act is to outright prohibit their use, which may contribute to exacerbating the same risks it is trying to curb. In fact, biometric categorisation systems are used to develop solutions to important challenges like safety, fairness, inclusions and youth protections for current and future AI systems. In order to preserve these beneficial uses, the best approach would be to include biometric categorisation as a high-risk use case (listed in Annex III), as pursued by the **Commission and the Council.**
Article 5(1), point (c)					
183	(c) the placing on the market, putting into	(c) the placing on the market, putting into service or use	(c) the placing on the market, putting into service or use	**Maintain the Commission's proposal**	**The Commission's proposal is the most suitable for the purpose.**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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:	of AI systems ~~by public authorities or on their behalf for the~~*for the social scoring* evaluation or classification of ~~the trustworthiness of natural persons~~*natural persons or groups thereof* over a certain period of time based on their social behaviour or known*, inferred* or predicted personal or personality characteristics, with the social score leading to either or both of the following:	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:	(c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following: **I**	The prohibition for law enforcement to leverage AI systems to perform "social scoring" or better " the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics" **(5(1)(c))** is desirable while being introduced for law enforcement use. Nonetheless, this should not be expanded to private actors. Private entities leverage AI for multiple purposes, including maintaining the safety and integrity of their systems. An analysis of previous user actions, for example prior purchases habits, previous login locations etc. are often crucial data in detecting and preventing fraud, removing malicious users from a platform in case of misbehaviour, prevent and address account impersonation etc. If this provision were to be extended to private actors - as suggested by both the Parliament and the Council - in the way it is currently formulated, the breadth of its

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
					scope would foreseeably deprive companies to leverage AI to pursue these important uses and certainly jeopardise the safety and integrity of AI systems and online platforms overall. If one of the goals of the AI Act is to ensure AI systems placed on the Union market and used are safe, restricting the ability of providers and developers to leverage this data to address these safety concerns is indeed counterproductive.
Article 5(1), point (da new)					
189a		*(da) the placing on the market, putting into service or use of an AI system for making risk assessments of natural persons or groups thereof in order to assess the risk of a natural person for offending or reoffending or for predicting the occurrence or reoccurrence of an actual or potential*		**Parliament's version** *(da) the placing on the market, putting into service or use of an AI system for making risk assessments of natural persons or groups thereof in order to assess the risk of a natural person for offending or reoffending or for predicting the occurrence or reoccurrence of an actual or potential*	Compared to the Commission's text, the **Parliament's addition is a positive development** in line with the risk-based approach that underpins the AI Act. In particular, introducing a prohibition of using AI systems to decide the level risk of someone who's been subjected to criminal proceedings is aligned with the spirit of Article 5 which seeks to prohibit the most risky uses of AI. Given the severe risk that similar AI systems can have on fundamental rights, it is

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		criminal or administrative offence based on profiling of a natural person or on assessing personality traits and characteristics, including the person's location, or past criminal behaviour of natural persons or groups of natural persons;		*criminal or administrative offence based on profiling of a natural person or on assessing personality traits and characteristics, including the person's location, or past criminal behaviour of natural persons or groups of natural persons;*	sensible to limit their use altogether.
Article 5(1), point (db new)					
189b		*(db) The placing on the market, putting into service or use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;*		**Parliament's version** *(db) The placing on the market, putting into service or use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;*	Compared to the Commission's text, the **Parliament's addition is a positive development** in line with the risk-based approach that underpins the AI Act.
Article 5(2), first subparagraph					
190	2. The use of		*2.* The use of	**Commission's version with amendments**	**The Commission's original draft** is a good start, but

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 point d) shall take into account the following elements:	*deleted*	'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:	The use of 'real-time' and **post** 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: OR **Parliament's version 5.1 (da)-(de).**	could use further improvement. In particular, when it comes to law enforcement use, it would be advisable to apply the prohibition to both real time and post remote biometric identification, given the impact it may have on fundamental rights. VP Vestager [1] has clarified that the intent of the provision is to prohibit mass surveillance, which has no place in our society. For this reason, we recommend ensuring the provision covers all the cases in which such practice may be carried out. In the alternative, **the proposal of the Parliament in points 5.1 (da)-(de) above** achieves this result in a more granular manner and is equally advisable.
Article 6					
199	Article 6 Classification rules for high-risk AI systems	Article 6 Classification rules for high-risk AI systems	*Article 6 Classification rules for high-risk AI systems*		
Article 6(1)					

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
200	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:	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:	*1. ~~Irrespective of whether~~ An AI system that is itself a product covered by the Union harmonisation legislation listed in Annex II shall be considered as high risk if it 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 above mentioned legislation.~~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:~~*	**Council's text with amendments** 1. ~~1.Irrespective of whether an~~ AI system **that is itself a product covered by the Union harmonisation legislation listed in Annex II shall be considered high-risk if** ~~it 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 above mentioned legislation.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:~~	As currently drafted, the AI Act assumes that AI systems have an elevated risk if they are themselves, or are intended to be used as safety components of, products required to undergo third-party conformity assessment. However, this assumption is faulty, because third-party conformity assessment are not necessarily dependent on the risk level of a product - they can also be required in certain cases simply because there are no applicable harmonised standards (e.g. under the Radio Equipment Directive), or where harmonised standards are available, if they can only be applied to the product in part. This legislative choice could lead to many AI systems inadvertently being classified as "high risk" merely because the product is not covered by harmonised standards, regardless of the actual risk they pose. This situation arises especially for new and innovative products, where standards have often not been developed yet. The current approach therefore

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
					introduces stricter requirements for AI systems in new and innovative products – regardless of the risks they effectively pose. Such an unintended consequence does not match with the AI Act's aim of fostering innovation and targeting only high-risk scenarios. Particularly, as proposed by the Commission, the provision ties the risk level of the AI system to whether the conformity assessment requires the involvement of a third party, whenever the product that the AI system is part of, must undergo such assessment. **The Council's text takes a step in the right direction** with improvements in the structure of the text, but still does not account for the cases where the conformity assessment simply is required for the lack of applicable standards, and therefore where this requirement does not accurately represent the risk level. These proposed edits aim at ensuring that a risk-based approach is enshrined in the

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
					criteria, by requiring that the AI System needs to go through said assessment whenever health, safety or fundamental rights are impacted and whenever the AI system is actually making final decisions. The suggested amendments to 6(1)(a) and 6(2)(a)**(below)** also seek to clarify that in order to be considered high-risk, the third-party conformity assessment must have been required because of the elevated risk associated with the product or technology. With our additions, we can circumscribe the applicability of this provision making sure the connection between the risk being addressed and the AI is a necessary criterion to trigger the conformity assessment, and so that there's an incentive to still include AI components in a product that could help make the product safer.
Article 6(1), point (a)					
201	(a) the AI system is intended to be	(a) the AI system is intended to be	*deleted*	**Amendment (NEW)** a) **It is required to**	See justification to 6(1)

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;	used as a safety component of a product, or *the AI system* is itself a product, covered by the Union harmonisation ~~legislation~~*law* listed in Annex II		**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 above mentioned legislation, except in cases where the requirement for third-party conformity arises only because the manufacturer has not applied, or has only partly applied, harmonised standards; and**	
Article 6(1), point (b)					
202	(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	(b) the product whose safety component *pursuant to point (a)* is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment *related*	*deleted*	**a) inherently poses a high risk to a person's psychological or physical safety; and b) (NEW) makes final decisions that result in such risk.**	See justification to 6(1)

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.	*to risks for health and safety,* with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation ~~legislation~~*law* listed in Annex II~~.~~*;*			
Article 6(2), first subparagraph					
203	2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.	~~2~~*1a*. In addition to the high-risk AI systems referred to in paragraph 1, AI systems *falling under one or more of the critical areas and use cases* referred to in Annex III shall ~~also~~*be considered high-risk if they pose a significant risk of harm to the health, safety or fundamental rights of natural persons. Where an AI system falls under Annex III point 2, it shall* be considered *to be high-risk if it poses*	2. ~~In addition to the high-risk AI systems~~*An AI system intended to be used as a safety component of a product covered by the legislation* referred to in paragraph 1~~, AI systems referred to in Annex III~~ shall be considered as high risk if it 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 above	**Parliament's text with amendments** ~~2~~*1a*. In addition to the high-risk AI systems referred to in paragraph 1, AI systems *falling under one or more of the critical areas and use cases* referred to in Annex III shall ~~also~~*be considered high-risk if they pose a significant risk of harm to the health, safety or fundamental rights of natural persons. Where an AI system falls under Annex III point 2, it shall* be considered *to be*	**The Parliament's text should be preferred.** In fact, compared to its other two counterparts, it introduces important criteria that circumscribe the applicability of Annex III, ensuring that a risk-based approach is enshrined in the criteria, by requiring there to be a high risk to a person's physical safety of fundamental rights be significantly jeopardized for the system to fall into a high-risk category.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		a significant risk of harm to the environment~~high-risk~~.	*mentioned legislation. This provision* shall ~~also be considered high-risk~~*apply irrespective of whether the AI system is placed on the market or put into service independently from the product*.	~~high-risk if it poses a significant risk of harm to the environment~~*high-risk*.	
Article 6(2), second subparagraph					
203a		*The Commission shall, six months prior to the entry into force of this Regulation, after consulting the AI Office and relevant stakeholders, provide guidelines clearly specifying the circumstances where the output of AI systems referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons or cases in which it would not.*		Parliament's version *The Commission shall, six months prior to the entry into force of this Regulation, after consulting the AI Office and relevant stakeholders, provide guidelines clearly specifying the circumstances where the output of AI systems referred to in Annex III would pose a significant risk of harm to the health, safety or fundamental rights of natural persons*	**This addition by the Parliament** is positive as it increases legal certainty and predictability for the subjects of the regulation, and ensures a multistakeholder approach.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				or cases in which it would not.	
Article 6(2), second subparagraph (new)					
203b			*2a. AI systems referred to in Annex III shall be considered high-risk unless the output of the system is purely accessory in respect of the relevant action or decision to be taken and is not therefore likely to lead to a significant risk to the health, safety or fundamental rights. In order to ensure uniform conditions for the implementation of this Regulation, the Commission shall, no later than one year after the entry into force of this Regulation, adopt implementing acts to specify the circumstances where the output of AI systems referred to in Annex III would be purely*	**Council's text with amendments** *2a. AI systems referred to in Annex III shall be considered high-risk ~~unless~~ only when they make final decisions that result in ~~the output of the system is purely accessory in respect of the relevant action or decision to be taken and is not therefore likely to lead to a~~ significant risk to the health, safety or fundamental rights. Final decisions shall be intended as outputs which influence the people and the environment with which the system interacts, and which is not subject to further human review. ~~In order to ensure uniform conditions~~*	It is understandable that the Council would want to provide additional guidelines across the requirements of the Act, particularly defining the cases where an AI system is indeed high risk and thus in scope of the Act. However, this structure is not the most appropriate to do so. There is a high level of uncertainty arising with waiting for the Commission to potentially qualify certain systems as accessory or not. Also, "accessory" is not a well defined term, with the consequence that the interpretation the Commission would give of it in its implementing acts cannot be easily predicted. All of this creates a legal uncertainty that would likely disincentivize investments and reduce innovation. While it is certainly the right move to circumscribe the applicability of Annex III to those decisions that indeed have an impact on health,

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
			accessory in respect of the relevant action or decision to be taken. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74, paragraph 2.	*for the implementation of this Regulation, the Commission shall, no later than one year after the entry into force of this Regulation, adopt implementing acts to specify the circumstances where the output of AI systems referred to in Annex III would be purely accessory in respect of the relevant action or decision to be taken. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74, paragraph 2.*	safety and fundamental rights, the recommended amendment highlights the need that the decision made by the AI System be **final** in order to qualify as high risk. A final decision is described as an output which influences the people and the environment with which the system interacts, and which is not subject to further human review. An important component to identify these high-risk AI Systems is precisely the ability to provide output by learning over time, unlike other types of software which produces outputs based on hard-coded, human written rules. The absence of a human reviewer is what makes certain AI systems high risk and what gives rise to the concerns and questions the Act is trying to address. Therefore, this inclusion is recommended for further clarity of scope and application.
Article 6(2a new)					
203c		*2a. Where providers falling*		**Parliament's text** *2a. Where providers*	The Parliament text allows for putting the AI system

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		**under one or more of the critical areas and use cases referred to in Annex III consider that their AI system does not pose a significant risk as described in paragraph 2, they shall submit a reasoned notification to the national supervisory authority that they are not subject to the requirements of Title III Chapter 2 of this Regulation. Where the AI system is intended to be used in two or more Member States, that notification shall be addressed to the AI Office. Without prejudice to Article 65, the national supervisory authority shall review and reply to the notification, directly or via the AI Office, within three months if they**		_**falling under one or more of the critical areas and use cases referred to in Annex III consider that their AI system does not pose a significant risk as described in paragraph 2, they shall submit a reasoned notification to the national supervisory authority that they are not subject to the requirements of Title III Chapter 2 of this Regulation. Where the AI system is intended to be used in two or more Member States, that notification shall be addressed to the AI Office. Without prejudice to Article 65, the national supervisory authority shall review and reply to the notification, directly or via the AI Office, within three months if they deem the AI system to be misclassified.**_	into service based on self assessment for high-risk classification. This will ensure that product deployments are not delayed whilst also providing reassurance to the public by reasoned notification to the AI office.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		deem the AI system to be misclassified.			
Article 6(2b new)					
203d		*2b. Providers that misclassify their AI system as not subject to the requirements of Title III Chapter 2 of this Regulation and place it on the market before the deadline for objection by national supervisory authorities shall be subject to fines pursuant to Article 71.*		**Delete (Maintain Commission & Council text)** ~~2b. Providers that misclassify their AI system as not subject to the requirements of Title III Chapter 2 of this Regulation and place it on the market before the deadline for objection by national supervisory authorities shall be subject to fines pursuant to Article 71.~~	The harsh penalties imposed on misclassification do not adequately represent the risk that the provision is trying to curb. A regime of this type will only deter investors and innovators from investing in Europe. In a novel and emerging field like AI, it is inevitable that it will take time for the regulation to be understood and interpreted. In general, it is advisable to maintain the **Commission version and hence to remove this provision.** If the legislator is keen to introduce a penalty regime for misclassification, a better approach would be, for example, to provide a certain grace period for misclassified providers to comply with the obligations of high risk systems.
Article 7					
204	Article 7 Amendments to Annex III	Article 7 Amendments to Annex III	*Article 7 Amendments to Annex III*		

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
Article 7(1)					
205	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~~**amend** Annex III by adding **or modifying areas or use-cases of** high-risk AI systems where ~~both of the following conditions are fulfilled:~~**these pose a significant risk of harm to health and safety, or an adverse impact on fundamental rights, to the environment, or to democracy and the rule of law, and that risk is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already**	*1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to* ~~*update*~~*amend the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:*	**Commission's text** 1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled:	**The Commission's original draft remains the best approach here.** Actors in the AI space need to have legal certainty to operate, and to be encouraged to innovate further. If a certain AI system can suddenly become high-risk, providers, developers and operators would be required to navigate at a high level of uncertainty and risk, which may discourage them to pursue certain products or services and curb innovation and technological development. Consequently, it is important to make the criteria that the Commission may use to introduce new high-risk AI systems well-defined and predictable. Compared to the original draft, the Parliament's proposal presents even less of this certainty. (Details below)

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		referred to in Annex III.			
Article 7(1), point (a)					
206	(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;	*deleted*	*(a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;*	**Maintain Commission's text** (a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III;	**The Commission's original draft remains the best approach.** By removing the topical requirement - which would demand that AI systems be used in the specific areas listed in Annex III for them to be eligible to be considered included as high risk - this new proposal is effectively making any AI system susceptible to a high risk determination. This adds a level of unpredictability that may be too burdensome, especially for smaller enterprises.
Article 7(1), point (b)					
207	(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,	*deleted*	*(b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk*	**Maintain Commission's text with amendments** (b) the AI systems ~~make final decisions that create a~~ **make final decisions that create a** ~~material high~~ risk of **material** harm to the health and safety, or a risk of **material** adverse impact on	It is also important to have very clear and granular criteria to be used to make the determination of high risk. These need not only to be defined, reliable and predictable, but also: a) consistent with the current spirit of Annex III; b) circumscribed to areas where there is effectively a high risk of material adverse

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.		*of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.*	fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of **material** harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.	impact to health, safety or fundamental rights AND c) limited to the cases where the AI system is making a final decision. The Commission's approach is certainly more suitable to pursue these goals, but could be amended to achieve them even further. The Parliament's decision to strike out the criteria completely, on the other hand, risks creating loopholes and confusion and should be reconsidered.
Article 7(1a)					
207a		*1a. The Commission is also empowered to adopt delegated acts in accordance with Article 73 to remove use-cases of high-risk AI systems from the list in Annex III if the conditions referred to in paragraph 1 no longer apply;*		Parliament's text *1a. The Commission is also empowered to adopt delegated acts in accordance with Article 73 to remove use-cases of high-risk AI systems from the list in Annex III if the conditions referred to in paragraph 1 no longer apply;*	**The Parliament's addition to the text is desirable.** By allowing the Commission to remove use cases that are no longer considered high-risk, the Act accounts for the evolving nature of the AI technology, which will foreseeably change in time, including reducing or even foregoing a lot of the risks that the Regulator is trying to curb with these provisions. This addition makes the Act more flexible and adaptable to time and technological developments.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	social circumstances, or age;	economic or social circumstances, or age;		age;	
Article 7(2), point (g)					
215	(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;	(g) the extent to which the outcome produced ~~with~~**involving** an AI system is easily reversible _or remedied_, whereby outcomes having an _adverse_ impact on _health, safety, fundamental rights of persons, the environment, or on democracy and rule of law_~~the health or safety of persons~~ shall not be considered as easily reversible;	(g) the extent to which the outcome produced with an AI system is **not** easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible;	**Maintain Parliament's text with amendments** g) the extent to which the outcome produced ~~with~~**involving** an AI system is easily reversible _or remedied_, whereby outcomes having an _adverse_ impact on _health, safety, fundamental rights of persons, the environment, or on democracy and rule of law_~~the health or safety of persons~~ shall not be considered as easily reversible;	**The Parliament's text is preferable here** because it circumscribes the level of risk to impacts that are actually _adverse_, and not _any_ impact. Our recommendation is to narrow down the subjects of the impact to _"health, safety and fundamental rights of persons"_ which is a consistent and well-understood standard throughout the Act but also in the EU legislation. Impact on the environment, democracy and the rule of law can be difficult, if not impossible, to adequately assess and measure, and to associate to a specific system. .
215a		_(ga) the extent of the availability and use of effective technical solutions_		**Maintain Commission's text** ~~(ga) the extent of~~	Reliability and corrigibility are not well understood or measurable concepts. These should not be included as

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		and mechanisms for the control, reliability and corrigibility of the AI system;		~~*the availability and use of effective technical solutions and mechanisms for the control, reliability and corrigibility of the AI system;*~~	criteria to determine high risk.
Article 7(2), point (gb new)					
215b		*(gb) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;*		**Maintain Parliament's text** *(gb) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;*	This amendment is welcomed because it denotes the importance of striking a balance between risks and benefits when making a high-risk determination.
Article 7(2), point (gc new)					
215c		*(gc) the extent of human oversight and the possibility for a human to intercede in order to override a decision or recommendations that may lead to potential harm;*		**Maintain Parliament's text** *(gc) the extent of human oversight and the possibility for a human to intercede in order to override a decision or recommendations that may lead to potential harm;*	This amendment is welcomed as it denotes the impact of human supervision and how that influences the risk level of a system. Striking a balance is crucial.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
Article 7(2), point (h)					
216	(h) the extent to which existing Union legislation provides for:	(h) the extent to which existing Union ~~legislation~~**law** provides for:	*(h) the extent to which existing Union legislation provides for:*		No comment
Article 7(2), point (h)(i)					
217	(i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;	(i) effective measures of redress in relation to the ~~risks posed~~**damage caused** by an AI system, with the exclusion of claims for **direct or indirect** damages;	*(i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;*	**Maintain Parliament's text** (i) effective measures of redress in relation to the ~~risks posed~~**damage caused** by an AI system, with the exclusion of claims for **direct or indirect** damages;	**The Parliament's version is preferable** because it anchors the measures to actual damage - a measurable criterion - rather than to a more generic risk, which could be unforeseeable or not measurable.
Article 7(2), point (h)(ii)					
218	(ii) effective measures to prevent or substantially minimise those risks.	(ii) effective measures to prevent or substantially minimise those risks.	*(ii) effective measures to prevent or substantially minimise those risks~~.~~;*		No comment
Article 7(2), point (ha)					
218a			*(ha) the magnitude and likelihood of benefit*	**Maintain Council's text** *(ha) the magnitude*	Similarly to what stated above in points (gb) and (gc) for the Parliament's version,

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
			of the AI use for individuals, groups, or society at large.	*and likelihood of benefit of the AI use for individuals, groups, or society at large.*	the **Council's amendment is welcomed** because it introduces a balancing factor that keeps in mind benefits and not only risks.
Article 7(2), point (h)(ii)					
218b		*2a. When assessing an AI system for the purposes of paragraphs 1 or 1a the Commission shall consult the AI Office and, where relevant, representatives of groups on which an AI system has an impact, industry, independent experts, the social partners, and civil society organisations. The Commission shall also organise public consultations in this regard and shall make the results of those consultations and of the final assessment publicly available;*		Maintain Parliament's text *2a. When assessing an AI system for the purposes of paragraphs 1 or 1a the Commission shall consult the AI Office and, where relevant, representatives of groups on which an AI system has an impact, industry, independent experts, the social partners, and civil society organisations. The Commission shall also organise public consultations in this regard and shall make the results of those consultations and of the final assessment publicly available;*	**The Parliament's amendment** is a desirable one and the right approach. In fact, it recognizes the importance of a multistakeholder approach to regulating AI, with the requirement for the Commission to gather perspectives of non-governmental stakeholders such as civil society and industry and to leverage their technical expertise, as well as to provide public insights around its decisions. It should therefore be endorsed.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
Article 7(2), point (h)(ii)					
218c			*2a. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list in Annex III by removing high-risk AI systems where both of the following conditions are fulfilled:*	**Council's text OR maintain Parliament's amendment 207a**	**The Council's additions in amendments 218c-e are very positive.** By allowing for specific situations where the Commission might remove certain AI systems for the high risk list, the Act is gaining flexibility and the possibility to better adapt to the fast-evolving technological landscape. It is also demonstrating that it's thinking about the technical progress and innovation that is likely to come and will foreseeably increase safety and reduce risks.
					The Parliament has adopted a similar approach at a different location (amendment 207a). While the two solutions are quite equivalent, given the option, the Parliament seems cleaner and more straightforward, since it does not introduce different requirements for the removal but simply allows it when the conditions of **7.1** are no longer met.
218d			*(a) the high-risk*		See above

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
			AI system(s) concerned no longer pose any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;		
218e			*(b) the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.*		See above
Article 7(2b new)					
218f		**2b. The AI Office, national supervisory authorities or the European Parliament may request the Commission to reassess and recategorise the risk categorisation of an AI systemin accordance with paragraphs 1 and 1a. The Commission shall**			No Comment.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		give reasons for its decision and make them public.			
Article 9					
223	Article 9 Risk management system	Article 9 Risk management system	*Article 9 Risk management system*		
Article 9(1)					
224	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems*, throughout the entire lifecycle of the AI system. The risk management system can be integrated into, or a part of, already existing risk management procedures relating to the relevant Union sectoral law insofar as it fulfils the requirements of this article*.	*1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.*	**Maintain Parliament's version** 1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems*, throughout the entire lifecycle of the AI system. The risk management system can be integrated into, or a part of, already existing risk management procedures relating to the relevant Union sectoral law insofar as it fulfils the requirements of*	A risk management system is desirable for high-risk AI systems. **The Parliament version is preferable** because it offers more flexibility to the providers to determine whether to rely on and/or adapt existing procedures and or create new ones.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				this article.	
Article 9(2)					
225	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:	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~~*review and* updating *of the risk management process, to ensure its continuing effectiveness, and documentation of any significant decisions and actions taken subject to this Article*. It shall comprise the following steps:	*2. The risk management system shall ~~consist of~~be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:*	**Commission Text with amendments** 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 **whenever there is a reasonable expectation of material change in the performance or impact of an AI system, including when an AI system moves to a different phase of the lifecycle or when the AI system is applied in a materially different way.** It shall comprise the following steps:	**The Commission's original text remains a good starting point here.** Our amendments aim at providing more certainty around risk management systems. In particular, the text includes more granular language around the requirements and the content of such risk management. For instance, it replaces "regular systematic updating" to "whenever there is a reasonable expectation of material change in the performance or impact of an AI system, including when an AI system moves to a different phase of the lifecycle or when the AI system is applied in a materially different way", providing a specific context and directions around when such updating is required.
Article 9(2), point (a)					
226	(a) identification	(a) identification**,**	*(a) identification*	**Council's text with amendments**	Compared to the

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	and analysis of the known and foreseeable risks associated with each high-risk AI system;	***estimation and evaluation*** ~~*and analysis*~~ of the known and ***the reasonably*** foreseeable risks ~~*associated with each*~~***that the high-risk AI system can pose to the health or safety of natural persons, their fundamental rights including equal access and opportunities, democracy and rule of law or the environement when the*** high-risk AI system ***is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse***;	*and analysis of the known and foreseeable risks* ~~*associated with each*~~***most likely to occur to health, safety and fundamental rights in view of the intended purpose of the*** *high-risk AI system;*	*(a) identification and analysis of the known and* reasonably *foreseeable* material *risks* ~~*associated with each*~~***most likely to occur to health, safety and fundamental rights in view of the intended purpose of the*** *high-risk AI system;*	Commission's text, the **Council makes an improvement** by clarifying what types of risks should be evaluated in the assessment. The amendments clarify the type of risks that should be evaluated, namely risks of material harm to health, safety and fundamental harm. This is a standard that appears recurrently throughout the Act and is therefore consistent with the remainder of the Regulation. The proposed amendments to the text aim at furthering said legal certainty even more by circumscribing the requirement to *reasonably* foreseeable and *material* ones.
Article 9(2), point (b)					
227	(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with	*deleted*	*deleted*	**Parliament and Council's version - deletion** ~~(b) estimation and evaluation of the risks that may emerge when the~~	

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	its intended purpose and under conditions of reasonably foreseeable misuse;			~~high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;~~	
Article 9(2), point (c)					
228	*(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;	*(c)* evaluation of ~~other possibly arising~~**emerging significant** risks *as described in point (a) and identified* based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;	*(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;*	**Commission and Council's text with amendments** c) evaluation of other possibly arising risks **of material harm to health, safety and fundamental rights** based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;	It is important to maintain the consistency of the risk criteria applied throughout the article, and the Regulation overall.
Article 9(2), point (d)					
229	(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.	(d) adoption of ~~suitable~~**appropriate and targeted** risk management measures **designed to address the risks identified pursuant to points a and b of**	*(d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.*	**Commission and Council text** (d) adoption of suitable risk management measures in accordance with the provisions of the following	

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		__this paragraph__ in accordance with the provisions of the following paragraphs.		paragraphs.	
229a			*The risks referred to in this paragraph shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.*	**Council text** *The risks referred to in this paragraph shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.*	**The Council takes the right approach** in specifying further which risks are expected to be subjected to risk mitigation procedures, increasing the legal certainty, predictability and foreseeability of legal requirements.
Article 9(3)					
230	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	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	*3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible ~~interactions~~interaction resulting from the combined*	**Council text with amendments** *3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible ~~interactions~~interaction resulting from the*	This paragraph includes a series of terms which, applied in the AI context, are vague and unclear, for example, "acceptable" residual risk, "suitable" testing procedures, and "appropriate balance". AI is not an area that benefits from extensive, existing best practices where those terms

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	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.	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~~*, with a view to mitigate risks effectively while ensuring an appropriate and proportionate implementation of the requirements*.	*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~~, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements*.	*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~~, with a view to minimising risks more effectively while ~~achieving an appropriate balance in~~ implementing the measures to fulfil those requirements*.	have an understood significance: rather, it is an area where standards and best practices are still emerging. Placing such unclear terms into regulation—without ensuring they have widely accepted meanings, will create profound legal uncertainty for AI developers and stifle innovation. **Both the Parliament and the Council make a significant improvement to the Commission text** by striking out the requirements of taking into account the "generally acknowledged state of the art", but they could go even further by, for example removing the "appropriate balance" concept to strengthen the legal certainty and feasibility around the requirements.
Article 9(4), first subparagraph					
231	4. The risk management measures referred to in paragraph 2, point (d) shall be such that any	4. The risk management measures referred to in paragraph 2, point (d) shall be such that	*4. The risk management measures referred to in paragraph 2, point (d) shall be such that any*	**Commission text**	The Commission text achieves the right balance of legal certainty, foreseeability, proportionality and technical feasibility.

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	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.	~~any~~**relevant** residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is **reasonably** judged **to be** acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks **and the reasoned judgements made** shall be communicated to the ~~user~~**deployer**.	*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*~~*.*		
Article 9(4), second subparagraph					
232	In identifying the most appropriate risk management measures, the following shall be ensured:	In identifying the most appropriate risk management measures, the following shall be ensured:	*In identifying the most appropriate risk management measures, the following shall be ensured:*		No comment
Article 9(4), second subparagraph, point (a)					
233	(a) elimination or	(a) elimination or	*(a) elimination or*	**Council's version**	**The Council's version** achieves the right balance of

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	reduction of risks as far as possible through adequate design and development;	reduction of *identified* risks as far as ~~possible~~*technically feasible* through adequate design and development *of the high-risk AI system, involving when relevant, experts and external stakeholders*;	*reduction of risks **identified and evaluated pursuant to paragraph 2** as far as possible through adequate design and development **of the high risk AI system**;*	*(a) elimination or reduction of risks **identified and evaluated pursuant to paragraph 2** as far as possible through adequate design and development **of the high risk AI system**;*	legal certainty, foreseeability, proportionality and technical feasibility.
Article 9(4), second subparagraph, point (b)					
234	(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;	(b) where appropriate, implementation of adequate mitigation and control measures ~~in relation to~~*addressing significant* risks that cannot be eliminated;	*(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;*	**Parliament text** (b) where appropriate, implementation of adequate mitigation and control measures ~~in relation to~~*addressing significant* risks that cannot be eliminated;	**The Parliament text** adds further nuance and positively circumscribes the scope of what's required.
Article 9(4), second subparagraph, point (c)					
235	(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in	(c) provision of ~~adequate~~*the required* information pursuant to Article 13, ~~in particular as regards the risks referred to in~~	*(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point*	**Parliament text**	**The Parliament text** adds granularity and specificity and positively circumscribes the scope of what's required. The change from users to deployers will depend on the rest of the Act and will need to be consistent with the rest

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	paragraph 2, point (b) of this Article, and, where appropriate, training to users.	~~paragraph 2, point (b) of this Article,~~ and, where appropriate, training to ~~users~~***deployers***.	*(b) of this Article, and, where appropriate, training to users.*		of the provisions.
Article 9(4), third subparagraph					
236	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.	In eliminating or reducing risks related to the use of the high-risk AI system, ~~due consideration~~***providers*** shall ~~be given to~~***take into due consideration*** the technical knowledge, experience, education~~, training to be expected by the user and the environment in which the system is intended to be used~~ ***and training the deployer may need, including in relation to the presumable context of use***.	*~~In~~**With a view to** 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.*	**Council's text with amendments** *~~In~~**With a view to** 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. **Consideration shall also be given to the overall utility of the high risk AI system itself, and how incorporating a risk mitigant into the design of the AI system would impact the AI system's overall functioning***	**The Council text** adopts a language that is softer and more flexible to accommodate the needs of a changing and evolving nature of the AI technology. In fact, risk assessment and mitigation certainly needs to be a *goal* to strive to, but complete *elimination* of risk is unfeasible. Additionally, it is important to acknowledge that any mitigating factors should be balanced out by keeping into account how they would affect the functioning of the AI systems and its utility. This amendment provides an important nuance and further clarity to the providers of high risk AI systems when conducting their risk assessment.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				or utility.	
Article 9(5)					
237	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.	5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate *and targeted* risk management measures *and weighing any such measures against the potential benefits and intended goals of the system*. 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.	*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~~in order to ensure that high-risk AI systems perform in a manner that is consistent with their intended purpose and they are in compliance with the requirements set out in this Chapter.*	**Parliament's version** 5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate *and targeted* risk management measures *and weighing any such measures against the potential benefits and intended goals of the system*. 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.	Amongst the three options, the **Parliament appears to be the most balanced one,** because it keeps into account the importance of weighing benefits to assess the right level of risk mitigation.
Article 9(6)					
238	6. Testing procedures shall	6. Testing procedures shall be	*6. Testing procedures ~~shall be~~*	**Commission's text** 6. Testing	**The Commission text** is the most preferable one in this

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.	suitable to achieve the intended purpose of the AI system ~~and do not need to go beyond what is necessary to achieve that purpose~~.	~~suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose~~*may include testing in real world conditions in accordance with Article 54a*.	procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.	particular case. In fact, the specificity and the caveat that testing procedures only need to be suitable to achieve the intended purpose of the AI system provide an adequate level of clarity and granularity for the providers to comply.
Article 9(7)					
239	7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the	7. The testing of the high-risk AI systems shall be performed, ~~as appropriate, at any point in time throughout the development process, and, in any event,~~ prior to the placing on the market or the putting into service. Testing shall be made against ~~preliminarily~~**prior** defined metrics**,** and probabilistic thresholds that are appropriate to the intended purpose *or*	7. *The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI*	**Commission & Council Text** 7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI	**The Commission's text, endorsed also by the Council**, provides the right level of caveats and flexibility to adapt to the evolving nature of AI systems.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	intended purpose of the high-risk AI system.	*reasonably foreseeable misuse* of the high-risk AI system.	*system.*	system.	
Article 9(8)					
240	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.	8. When implementing the risk management system described in paragraphs 1 to 7, ~~specific consideration shall be given~~*providers shall give specific consideration* to whether the high-risk AI system is likely to ~~be accessed by or have an impact on~~*adversely impact vulnerable groups of people or* children.	*8. ~~When implementing~~The risk management system described in paragraphs 1 to 7~~,~~ ~~specific consideration shall be given~~ shall give specific consideration to whether the high-risk AI system is likely to be accessed by or have an impact on ~~children~~persons under the age of 18.*	**Council's text** *8. ~~When implementing~~The risk management system described in paragraphs 1 to 7~~,~~ ~~specific consideration shall be given~~ shall give specific consideration to whether the high-risk AI system is likely to be accessed by or have an impact on ~~children~~persons under the age of 18.*	**The Council takes the right approach here** both in a linguistic structure and provides additional clarity by specifying the exact category of people (including both vulnerable groups of people and children).
Article 9(9)					
241	9. For credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to	9. For *providers and AI systems already covered by Union law that require them to establish a specific risk management,*	*9. For ~~credit institutions regulated by Directive 2013/36/EU~~provide rs of high-risk AI systems that are*	**Parliament's version** 9. For *providers and AI systems already covered by Union law that require them to establish a*	It is a good choice to give AI system providers the flexibility to incorporate the risk management procedure that they are required to pursue under article 9 into an already existing risk management process. **The**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.	*including* credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of *or combined with* the risk management procedures established by ~~those institutions pursuant to Article 74 of that Directive~~*that Union law*.	*subject to requirements regarding internal risk management processes under relevant sectorial Union law, the aspects described in paragraphs 1 to 8* ~~shall~~*may be part of the risk management procedures* established ~~by those institutions~~ pursuant to ~~Article 74 of that Directive~~*that law*.	*specific risk management, including* credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of *or combined with* the risk management procedures established by ~~those institutions pursuant to Article 74 of that Directive~~*that Union law*.	**Parliament's approach appears to be the right one in this case,** because it expands the scope of the provision to other providers that are required to undergo risk management procedures under Union law, rather than limiting it to the Credit Institutions. This empowers providers to decide whether to comply with their cumulative obligations under Union Law with separate risk management processes, or with one that covers all the obligations together. Such choice is important because providers have the best knowledge of their AI systems and of how to mitigate their risk.
Article 10					
242	Article 10 Data and data governance	Article 10 Data and data governance	*Article 10 Data and data governance*		
Article 10(1), first subparagraph					
243	1. High-risk AI systems which make use of techniques involving the training of models	1. High-risk AI systems which make use of techniques involving the training of models	*1. High-risk AI systems which make use of techniques involving the training of models with data shall be*	**Parliament's version** 1. High-risk AI systems which make use of techniques	The Parliament's text is the best choice here, because it provides the right contextual and feasibility nuance level.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.	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 *as far as this is technically feasible according to the specific market segment or scope of application*.	*developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.*	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 *as far as this is technically feasible according to the specific market segment or scope of application*.	
Article 10(1), second subparagraph new					
243a		*Techniques that do not require labelled input data such as unsupervised learning and reinforcement learning shall be developed on the basis of data sets such as for testing and verification that meet the quality criteria referred to in paragraphs 2 to 5.*		**Parliament's version** *Techniques that do not require labelled input data such as unsupervised learning and reinforcement learning shall be developed on the basis of data sets such as for testing and verification that meet the quality criteria referred to in paragraphs 2 to 5.*	**The Parliament's amendment** is a positive improvement. It offers nuances across different types of AI systems and ensures the requirements are tailored to the risk-level.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
Article 10(2)					
244	2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,	2. Training, validation and testing data sets shall be subject to ~~appropriate~~ data governance ~~and management practices~~*appropriate for the context of use as well as the intended purpose of the AI system*. Those ~~practices~~*measures* shall concern in particular,	2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular*:*:	**Parliament's version** 2. Training, validation and testing data sets shall be subject to ~~appropriate~~ data governance ~~and management practices~~*appropriate for the context of use as well as the intended purpose of the AI system*. Those ~~practices~~*measures* shall concern in particular,	**The Parliament was receptive** to the need to address a series of problems with the original Commission text and made important amendments. In particular, the addition of context and purposes of the AI system as nuances to the data governance measures is an important one.
Article 10(2), point (a)					
245	(a) the relevant design choices;	(a) the relevant design choices;	(a) the relevant design choices;	**Amendment** (a) the relevant design choices **where relevant;**	Meta's suggested amendment offers further flexibility and ensures nuance with technical feasibility.
Article 10(2), point (aa new)					
245a		*(aa) transparency as regards the original purpose of data collection;*		**Maintain Commission and Council version** ~~(aa) transparency as regards the original purpose of~~	This addition by the Parliament is redundant, because data collection is already covered by 10(2)b. **The Commission's original text** should be maintained.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				~~*data collection;*~~	
Article 10(2), point (b)					
246	(b) data collection;	(b) data collection ***processes***;	*(b) data collection **processes**;*	**Maintain Commission version** (b) data collection;	**The original version by the Commission is clearer and more straightforward**. The concepts of data collection and data processing are well established, so this word combination risks creating confusion.
Article 10(2), point (c)					
247	(c) relevant data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;	(c) ~~*relevant*~~ data preparation processing operations, such as annotation, labelling, cleaning**,** ***updating***, enrichment and aggregation;	*(c) relevant data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;*	**Parliament's version** (c) ~~*relevant*~~ data preparation processing operations, such as annotation, labelling, cleaning**, *updating***, enrichment and aggregation;	Meta's addition of "updating" to the **Parliament's version** is an appropriate one to add granularity and clarity.
Article 10(2), point (d)					
248	(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to	(d) the formulation of ~~*relevant*~~ assumptions, notably with respect to the information that the data are supposed to measure and represent;	*(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;*	**Maintain Commission version** (d) the formulation of relevant assumptions, notably with respect to the information that the	It is most appropriate to maintain the relevancy requirement for nuance and for careful circumscription of scope. **The Commission's original version remains, thus, the best one.**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	measure and represent;			data are supposed to measure and represent;	
Article 10(2), point (e)					
249	(e) a prior assessment of the availability, quantity and suitability of the data sets that are needed;	(e) ~~a prior~~an assessment of the availability, quantity and suitability of the data sets that are needed;	*(e) a prior assessment of the availability, quantity and suitability of the data sets that are needed;*	**Maintain Parliament's version** (e) ~~a prior~~an assessment of the availability, quantity and suitability of the data sets that are needed;	**The Parliament version** offers more flexibility by removing the "prior" requirements and thus allowing assessments at different times where appropriate.
Article 10(2), point (f)					
250	(f) examination in view of possible biases;	(f) examination in view of possible biases **_that are likely to affect the health and safety of persons, negatively impact fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations ('feedback loops')_**	*(f) examination in view of possible biases **that are likely to affect health and safety of natural persons or lead to discrimination prohibited by Union law;***	**Maintain Council version** *(f) examination in view of possible biases **that are likely to affect health and safety of natural persons or lead to discrimination prohibited by Union law;***	**The Council's additions** are important to anchor the bias examination to specific legal criteria. This is particularly important in the case of bias of AI systems, which is an area where a lot of work is still underway. Understanding what it means for an AI system to be "fair," developing tools for measuring potential bias, to develop approaches for mitigating bias, and to create frameworks to help us balance competing equities and values—work that is still ongoing today. In an area

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		and appropriate measures to detect, prevent and mitigate possible biases;			that already has so much vagueness and uncertainty, giving clear guidelines that clarify what exact issues the legislator is purporting to address will enable providers to comply more easily, with benefits for safety and also innovation.
Article 10(2), point (fa new)					
250a		*(fa) appropriate measures to detect, prevent and mitigate possible biases;*			No comment
Article 10(2), point (g)					
251	(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.	(g) the identification of ~~any possible~~*relevant* data gaps or shortcomings *that prevent compliance with this Regulation*, and how those gaps and shortcomings can be addressed.	(g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.	**Amendment** (g) the identification of any possible data gaps or shortcomings **that materially increase the risks of harm to the health, safety and fundamental rights,** and how those gaps and shortcomings can be addressed	The amendment we have provided ensures the same criteria of harm to health, safety and fundamental rights that is recurrent throughout the Act is adopted here too. This ensures consistency of expectations and legal certainty.
Article 10(3)					
252	3. Training,	3. Training	3. Training,	**Parliament's version with**	**The Parliament's text**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.	***datasets, and where they are used***, validation and testing ~~data sets~~***datasets, including the labels,*** shall be relevant, ***sufficiently*** representative, ~~free of~~***appropriately vetted for*** errors and ***be as*** complete ***as possible in view of the intended purpose***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons ~~on which~~***in relation to whom*** the high-risk AI system is intended to be used. These characteristics of the ~~data sets may~~***datasets shall*** be met at the level of individual ~~data sets~~***datasets*** or a combination thereof.	*validation and testing data sets shall be relevant, representative,* **and to the best extent possible,** *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.*	**amendments** 3. Training ***datasets, and where they are used***, validation and testing ~~data sets~~***datasets, including the labels,*** **to the extent technically feasible** shall be relevant, ~~sufficiently~~ ***appropriately*** representative, ~~free of~~***appropriately vetted for*** errors and ***be as*** complete ***as possible necessary in view of the intended purpose*** and context in which it will be deployed. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons ~~on which~~***in relation to whom*** the high-risk AI system is intended to be used. These characteristics of the ~~data sets may~~***datasets shall*** be met at the level of	**appears** to be responsive to some of the major issues that were present in the Commission's text. In particular, the Parliament has added important nuances to the datasets requirement such as "sufficiently" representative, "appropriately vetted" and "as complete as possible in view of the intended purpose". However, the final version could be improved even further, particularly ensuring that there is a safety net for technical feasibility. In particular, the following criteria should be taken into consideration: 1) *appropriately* representative added to ensure that the context is being taken into account. 2) *to the extent technically feasible* to keep into consideration the state of the art. *3) complete as necessary in view of the intended purpose and context,* in order to underline that the "completeness" level is not a one-size-fits-all. Rather, it may vary - and should be looked at - based on the context in which the AI

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				individual ~~data sets~~*datasets* or a combination thereof.	system is deployed and on the function that the AI system is meant to pursue.
Article 10(4)					
253	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.	4. ~~Training, validation and testing data sets~~*Datasets* shall take into account, to the extent required by the intended purpose *or reasonably foreseeable misuses of the AI system*, the characteristics or elements that are particular to the specific geographical**,** *contextual*, behavioural or functional setting within which the high-risk AI system is intended to be used.	*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.*	**Maintain Commission & Council version** 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.	
Article 10(5), first subparagraph					
254	5. To the extent that it is strictly necessary for the purposes of ensuring bias	5. To the extent that it is strictly necessary for the purposes of ensuring ~~bias~~	*5. To the extent that it is strictly necessary for the purposes of ensuring bias*	**Maintain Commission & Council version with amendments** 5. To the extent that	**The Commission and the Council took the right approach here** by introducing an additional legal basis for processing

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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	~~monitoring,~~ ***negative bias*** detection and correction in relation to the high-risk AI systems, the providers of such systems may ***exceptionally*** 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***.*** ***In particular, all the following conditions shall apply in order for this processing to***	*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.*	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, ***on the basis of Article 9(2)(g) of Regulation (EU) 2016/679, Article 10(a) of Directive (EU) 2016/680 and Article 10(2)(g) of Regulation (EU) 2018/1725, respectively,*** subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the	sensitive categories of data to detect and monitor bias. Parliament's decision to strictly restrict its applicability to a series of very specific criteria will severely limit the flexibility and choice that providers have, and likely have a negative effect on the very measurement of the bias that the article is encouraging. Lacking a specific legal basis in GDPR article 9 to use data for this purpose, and without an exemption for the processing of special categories of data, providers would effectively be prevented from achieving bias mitigation and monitoring, which is a key objective of the Act. The suggested wording is to ensure that it is clear that there is a valid legal basis to process this data, which is defendable to the relevant data protection authorities. The importance of performing bias monitoring and mitigation operations is acknowledged multiple times in the Act. It is impossible to correct a problem if it cannot

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	, or encryption where anonymisation may significantly affect the purpose pursued.	*occur:* ~~measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.~~		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.	be measured, detected, or monitored, and this presents a fundamental tension in addressing bias in AI systems. Detecting bias that affects vulnerable populations often requires collecting and storing special categories of personal data (e.g., race and ethnicity) so that system providers and maintainers can assess how the system is performing for certain categories of people. Restricting the possibility of the providers to process special categories of data for this purpose, in spite of all the safeguards that would still be in place for said processing (eg. pseudonymisation, encryption…), would in practice functionally prevent compliance with the very obligation that the Act is setting forth and ultimately undermine the Act's objective of preventing harm and unfair discrimination in AI systems. Relying on existing legal bases in GDPR, such as consent, would potentially defeat the objective to

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
					achieve bias prevention and even exacerbate it as the measurement would fall foul of selection bias. Therefore, the original text should be the final one, with the additional clarification added to ensure the text is clear on what legal basis is provided for.
Article 10(5), first subparagraph, point (a new)					
254a		*(a) the bias detection and correction cannot be effectively fulfilled by processing synthetic or anonymised data;*		**Maintain Commission & Council version & Delete the new provision introduced by the EP.** *(a) the bias detection and correction cannot be effectively fulfilled by processing synthetic or anonymised data;*	See above
Article 10(5), first subparagraph, point (b new)					
254b		*b) the data are pseudonymised;*		**Maintain Commission & Council version & Delete the new provision**	See above

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				introduced by the EP *b) the data are pseudonymised;*	
Article 10(5), first subparagraph, point (c new)					
254c		*(c) the provider takes appropriate technical and organisational measures to ensure that the data processed for the purpose of this paragraph are secured, protected, subject to suitable safeguards and only authorised persons have access to those data with appropriate confidentiality obligations;*		**Maintain Commission & Council version & (Delete) the new provision introduced by the EP** *(c) the provider takes appropriate technical and organisational measures to ensure that the data processed for the purpose of this paragraph are secured, protected, subject to suitable safeguards and only authorised persons have access to those data with appropriate confidentiality obligations;*	See above
Article 10(5), first subparagraph, point (d new)					

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
254d		*(d)* *the data processed for the purpose of this paragraph are not to be transmitted, transferred or otherwise accessed by other parties;*		**Maintain Commission & Council version & Delete the new provision introduced by the EP** *(d) the data processed for the purpose of this paragraph are not to be transmitted, transferred or otherwise accessed by other parties;*	See above
Article 10(5), first subparagraph, point (e new)					
254e		*(e)* *the data processed for the purpose of this paragraph are protected by means of appropriate technical and organisational measures and deleted once the bias has been corrected or the personal data has reached the end of its retention period;*		**Maintain Commission & Council version & Delete the new provision introduced by the EP** *(e) the data processed for the purpose of this paragraph are protected by means of appropriate technical and organisational measures and deleted once the bias has been corrected*	See above

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
				~~or the personal data has reached the end of its retention period;~~	
Article 10(5), first subparagraph, point (f new)					
254f		_(f) effective and appropriate measures are in place to ensure availability, security and resilience of processing systems and services against technical or physical incidents;_		**Maintain Commission & Council version & Delete the new provision introduced by the EP** ~~(f) effective and appropriate measures are in place to ensure availability, security and resilience of processing systems and services against technical or physical incidents;~~	See above
Article 10(5), first subparagraph, point (g new)					
254g		_(g) effective and appropriate measures are in place to ensure physical security of locations where the data are stored and processed, internal IT and IT security_		**Maintain Commission & Council version & Delete the new provision introduced by the EP** ~~(g) effective and appropriate~~	See above

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		governance and management, certification of processes and products;		*measures are in place to ensure physical security of locations where the data are stored and processed, internal IT and IT security governance and management, certification of processes and products;*	
Article 10(5), second subparagraph new					
254h		*Providers having recourse to this provision shall draw up documentation explaining why the processing of special categories of personal data was necessary to detect and correct biases.*		**Maintain Commission & Council version & Delete the new provision introduced by the EP** *Providers having recourse to this provision shall draw up documentation explaining why the processing of special categories of personal data was necessary to detect and correct biases.*	See above
Article 10(6)					
255	6. Appropriate	6. Appropriate data	6. *Appropriate*	**Maintain Commission**	**The original approach by**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.	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.	~~data governance and management practices shall apply~~ *For the development of high-risk AI systems ~~other than those which make use of~~not using techniques involving the training of models*, **paragraphs 2 to 5 shall apply only to the testing data sets** ~~in order to ensure that those high-risk AI systems comply with paragraph 2~~.	version 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.	**the Commission, followed also by the Parliament,** allows more flexibility, as the providers have more room to determine the appropriateness of data governance measures for the training model of their specific system. Giving this flexibility ensures that the practices can be adjusted and tailored to the purpose, content and risk accordingly.
Article 10(6a new)					
255a		***6a.*** ***Where the provider cannot comply with the obligations laid down in this Article because that provider does not have access to the data and the data is held exclusively by the deployer, the deployer may, on the basis of a contract, be made responsible for any***		Maintain Commission and Council's version (delete) ~~*6a. Where the provider cannot comply with the obligations laid down in this Article because that provider does not have access to the data and the data is held exclusively by the deployer, the*~~	**The original approach by the Commission, followed also by the Council**, allows for freedom of contract and should be followed. Introducing this potential contractual provision appears to run contrary to the freedom to contract and introduces an unnecessary potential for a strict liability clause, which may be unworkable in many jurisdictions.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		infringement of this Article.		*deployer may, on the basis of a contract, be made responsible for any infringement of this Article.*	
Article 11					
256	Article 11 Technical documentation				
Article 11(1), first subparagraph					
257	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.			*No comment*	
Article 11(1), second subparagraph					
258	The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies			**Amendment** The technical documentation shall ~~be drawn up in such a way to demonstrate that the high-risk AI system~~	Predictability, certainty and clarity should underpin the obligation to maintain technical documentation for high-risk AI systems. Referencing the list of documents highlighted in

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.			~~complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall~~ contain, at a minimum, the elements set out in Annex IV, **or, in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent authority.**	Annex IV achieves such purposes. Moreover, introducing more flexible alternatives for smaller companies which may not have the same resources. Such flexibility for SMEs is essential in promoting growth and innovation.
Article 11(2)					
259	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			*No comment*	

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.				
Article 11(3)					
260	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.			*No comment*	
Article 11(3a new)					

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
260a		_**3a. 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.**_		_No comment_	
Article 12					
261	Article 12 Record-keeping	_Article 12 Record-keeping_	_Article 12 Record-keeping_		
Article 12(1)					
262	1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs')	_1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk_	_1. High-risk AI systems shall be designed and developed with capabilities enabling**technically allow for** the automatic recording of events ('logs')_	**Commission's version with amendments** 1. High-risk AI systems shall be designed and developed with capabilities enabling	The Commission draft of article 12 presents some problems. Notably, what exactly is required in terms of record keeping is unclear: logs are not defined, nor is the purpose for their preservation, and other factors like privacy and

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.	*AI systems is operating. Those logging capabilities shall conform to **the state of the art and** recognised standards or common specifications.*	*while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications***over the duration of the life cycle of the system**.	the automatic recording of **AI system inputs and outputs ('logs') events ('logs')** while the high-risk AI systems **are** operating, **to the extent technically feasible and to the extent that such records can be preserved in a privacy-preserving manne**r. Those ~~logging capabilities~~ **logs** shall conform to recognised standards or common specifications.	technical feasibility are not kept into account. First, the meaning of "logs" needs to be clarified. The suggested amendment achieves this purpose by defining it as "an AI system inputs and outputs".
Article 12(2)					
263	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.	*2. ~~The logging capabilities shall~~**In order to** ensure a level of traceability of the AI system's functioning throughout its ~~lifecycle~~**entire lifetime** that is appropriate to the intended purpose of the system**, the logging capabilities shall facilitate the***	*2. ~~The logging capabilities shall~~**In order to** ensure a level of traceability of the AI system's functioning ~~throughout its lifecycle~~ that is appropriate to the intended purpose of the system~~.~~**, logging capabilities shall enable the recording of events***	**Amendment** The ~~logging capabilities~~ **logs** shall **enable the inputs and outputs of the high-risk AI system to be auditable with respect to the risks evaluated in Article 9(2),** ~~ensure a level of traceability of the AI system's functioning~~ throughout its	The edits suggested replace the standard of traceability with that of "auditability". This is a standard that better fits the objective of the requirement - namely, to ensure an adequate monitoring of the systems with respect to high risks it may cause.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		monitoring of operations as referred to in Article 29(4) as well as the post market monitoring referred to in Article 61. *In particular, they shall enable the recording of events relevant for the identification of situations that may:*	*relevant for:*	lifecycle **and as** ~~that is~~ appropriate to the intended purpose of the system**, to the extent technically feasible and to the extent that such records can be preserved in a privacy-preserving manner.**	
Article 12(2), point (a new)					
263a		*(a)* *result in the AI system presenting a risk within the meaning of Article65(1); or*		**Delete - Maintain Commission's version** ~~a) result in the AI system presenting a risk within the meaning of Article65(1); or~~	
Article 12(2), point (b new)					
263b		*(b)* *lead to a substantial modification of the AI system.*		**Delete - Maintain Commission's version** ~~(b) lead to a substantial modification of the AI system.~~	

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
263c			*(i) identification of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or in a substantial modification;* *(ii) facilitation of the post-market monitoring referred to in Article 61; and* *(iii) monitoring of the operation of high-risk AI systems referred to in Article 29(4).*	Delete - Maintain Commission's version	
Article 12(2a new)					
263d		*2a. High-risk AI systems shall be designed and developed with, the logging capabilities enabling the recording of energy consumption, the measurement or calculation of resource use and environmental impact of the high-risk AI system during all phases of*		Delete - Maintain Commission's version *2a. High-risk AI systems shall be designed and developed with, the logging capabilities enabling the recording of energy consumption, the measurement or calculation of resource use and environmental impact*	**The Commission's approach remains appropriate and relevant here.** Risk level does not correlate to energy consumption. If the goal is to improve transparency about the environmental impact of AI development, it would be better to do this at an organisation level, rather than at a system one. This is more achievable (it is difficult, if not technically impossible, to isolate the

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		the system's lifecycle.		*of the high-risk AI system during all phases of the system's lifecycle.*	energy consumption of a single system) and would also capture resource-intensive low-risk systems, rather than focusing only on high-risk systems which may in fact be less energy intensive than low-risk ones. Thus we believe that amendments related to environmental impact may be better integrated in the legislation supporting the implementation of the Green Deal. We believe that overlapping provisions with the existing sustainability framework should be avoided for compliance clarity.
Article 12(3)					
264	3. In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of	*deleted*	*deleted*	**Commission's version, with amendments** 3. In particular, ~~logging capabilities~~ **logs** shall enable the monitoring of the operation of the high-risk AI system with respect to the	Also in this case, the **Commission's text** is the most appropriate approach. The amendments made aim at introducing important caveats such as privacy and trade secret preservations, as well as technical feasibility. These are crucial to ensure the continuation of innovation, the certainty of

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.			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. **For records constituting trade secrets as defined in Article 2 of Directive (EU) 2016/943, or personal information as defined in GDPR, provider may elect to confidentially provide such trade secrets only to relevant public authorities to the extent necessary for such authorities to perform their obligations hereunder.**	the legal requirements and the correct balance with other important policy objectives.
Article 12(4)					
265	4. For high-risk AI systems	4. For high-risk AI systems referred to	4. For high-risk AI systems referred to	**Delete** ~~4. For high-risk AI systems referred to in~~	Paragraph 4 should be deleted. Adding specific requirements only for one

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:	*in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:*	*in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:*	*paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:*	subset of high-risk systems is unnecessary and does not reflect any specific risk. It also does not respond to a particular requirement. Also, most of these requirements clash with other privacy principles, such as data minimization.
Article 12(4), point (a)					
266	(a) recording of the period of each use of the system (start date and time and end date and time of each use);	*(a) recording of the period of each use of the system (start date and time and end date and time of each use);*	*(a) recording of the period of each use of the system (start date and time and end date and time of each use);*	**Delete** *(a) recording of the period of each use of the system (start date and time and end date and time of each use);*	See above
Article 12(4), point (b)					
267	(b) the reference database against which input data has been checked by the system;	*(b) the reference database against which input data has been checked by the system;*	*(b) the reference database against which input data has been checked by the system;*	**Delete** *(b) the reference database against which input data has been checked by the system;*	See above
Article 12(4), point (c)					
268	(c) the input data for which the search has led to a match;	*(c) the input data for which the search has led to a match;*	*(c) the input data for which the search has led to a match;*	**Delete** *(c) the input data for which the search has led to a match;*	See above
Article 12(4), point (d)					
269	R (d) the	*(d) the*	*(d) the*	**Delete**	See above

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).	*identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).*	*identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).*	*(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5)*	
Article 13					
270	Article 13 Transparency and provision of information to users	*Article 13 Transparency and provision of information to users*	*Article 13 Transparency and provision of information to users*		*No comment*
Article 13(1), first subparagraph					
271	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	*1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable **providers and** users to interpret **reasonably understand** the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured **functioning. Appropriate***	*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*	**Commission's version with amendments** 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**	It is undoubtedly important to provide an adequate level of transparency to users of AI systems, to allow both user and provider to comply with their own obligations under the Act. Nonetheless the original formulation of the text is unclear and prone to uncertainty. In an emerging field like AI, the meaning of terms such as "appropriately" is not well-established or generally understood. On the contrary, AI is not an area that benefits from extensive, existing best practices where those terms have an understood significance: rather, it is an

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.	*transparency shall be ensured in accordance with the intended purpose of the AI system*, with a view to achieving compliance with the relevant obligations of the ~~user and of the~~ ~~provider~~*provider and user* set out in Chapter 3 of this Title.	*the provider set out in Chapter 3 of this Title **and enabling users to understand and use the system appropriately**.*	~~view to achieving compliance~~ **enable the user and the provider to comply** with thei**r** relevant obligations ~~of the user and of the provider~~ set out in Chapter 3 of this Title.	area where standards and best practices are still emerging. For this reason, it is best to anchor the requirements to criteria that can be objectively interpreted and applied. For this reason, the amendment proposed ties the transparency level to what the user needs in order to comply, in turn, with their respective obligations. This will provide more clarity and certainty.
Article 13(1), second subparagraph new					
271a		*Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall be enabled to*		**Maintain Commission's version** - delete ~~Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall~~	Similarly to the reasoning above, this subparagraph includes unclear terms and undefined criteria, such as "interpretable", "appropriately" and "affected person". For these reasons, this subparagraph does not add clarity to the rest of the article: if anything, it creates more uncertainty. As a result, it is advisable to remove it and **reverse the Commission's original draft, followed by the Council.**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, allowing the user to explain the decisions taken by the AI system to the affected person pursuant to Article 68(c).		*be enabled to understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, allowing the user to explain the decisions taken by the AI system to the affected person pursuant to Article 68(c).*	

Article 13(2)

| 272 | 2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users. | 2. High-risk AI systems shall be accompanied by *intelligible* instructions for use in an appropriate digital format or *made* otherwise *available in a durable medium* that include concise, ~~complete, correct and clear~~*correct, clear and to the extent possible complete* information that *helps operating and maintaining the AI* | 2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users. | **Commission text with amendments**

High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users, **to assist them in operating and maintaining the system where appropriate, taking** | The Commission's approach, also followed by the Council, is the most appropriate for this particular article, but it could use some additional explanation. In particular, the proposed amendment adds granularity and nuance by contextualizing the requirement, clarifying the purpose to put the user in the position to comply with the Act and underlining the importance of the system's intended use and targeted audience. |

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		system as well as supporting informed decision-making by users and is reasonably~~is~~ relevant, accessible and comprehensible to users.		**into consideration the system's intended purpose and the expected audience for the instructions.**	
Article 13(3)					
273	3. The information referred to in paragraph 2 shall specify:	3. *To achieve the outcomes referred to in paragraph 1,~~The~~ information referred to in paragraph 2 shall specify:*	3. *The information referred to in paragraph 2 shall specify:*		*No comment*
Article 13(3), point (a)					
274	(a) the identity and the contact details of the provider and, where applicable, of its authorised representative;	*(a) the identity and the contact details of the provider and, where applicable, of its authorised ~~representative~~representatives;*	*(a) the identity and the contact details of the provider and, where applicable, of its authorised representative;*	**Maintain Commission's version**	
Article 13(3), point (aa new)					
274a		*(aa) where it is not the same as the provider, the identity and the contact details of the entity that*		**Maintain Commission's version**	

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		carried out the conformity assessment and, where applicable, of its authorised representative;			
Article 13(3), point (b)					
275	(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:	*(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including, where appropriate:*	*(b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including:*	**Maintain Commission's version**	
Article 13(3), point (b)(i)					
276	(i) its intended purpose;	*(i) its intended purpose;*	*(i) its intended purpose, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;*	**Maintain Commission's version**	
Article 13(3), point (b)(ii)					
277	(ii) the level of accuracy, robustness and cybersecurity	*(ii) the level of accuracy, robustness and cybersecurity*	*(ii) the level of accuracy, including its metrics, robustness and*	**Delete** ~~(ii) the level of accuracy, robustness and cybersecurity referred to in Article~~	3 (ii) is already encompassed by 3(iii) and therefore does not need to be reiterated.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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;	*referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any* **clearly** *known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;*	*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;*	~~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;~~	
Article 13(3), point (b)(iii)					
278	(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	*(iii) any* **clearly** *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*__**.**__	*(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*	**Council text** *(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* ***referred to in Article***	The Council text is the most appropriate here. In fact, they chose to make the text as clear and objective as possible, by making the requirements consistent and anchored to the risk management system.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	safety or fundamental rights;	***fundamental rights or the environment, including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used*** ~~*or fundamental rights*~~*;*	*referred to in Article 9(2);*	***9(2);***	
Article 28					
374	Article 28 Obligations of distributors, importers, users or any other third-party	*Article 28* ~~*Obligations of*~~ ***Responsibilities along the AI value chain of providers,*** *distributors, importers,* ~~*users or any*~~ ***deployers or*** *other* ~~*third-party*~~ ***third parties***	*deleted*		
Article 28(1)					
375	*1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and*	*1. Any distributor, importer,* ~~*user*~~***deployer*** *or other third-party shall be considered a provider* ***of a high-risk AI system*** *for the purposes of this Regulation and*	*deleted*		

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:	*shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:*			
Article 28(1), point (a)					
376	*(a)* they place on the market or put into service a high-risk AI system under their name or trademark;	*(a)* they ~~place on the market or put into service~~**put their name or trademarkt on** a high-risk AI system ~~under their name or trademark~~**already placed on the market or put into service**;	*deleted*		
Article 28(1), point (b)					
377	*(b)* they modify the intended purpose of a high-risk AI system already placed on the market or put into service;	*(b)* they ~~modify the intended purpose of~~**make a substantial modification to** a high-risk AI system **that has** already **been** placed on the market or **has already been** put into service **and in a way that it remains a high-risk**	*deleted*		

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		AI system in accordance with Article 6;			
377a		*(ba) they make a substantial modification to an AI system, including a general purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such manner that the AI system becomes a high risk AI system in accordance with Article 6*			
Article 28(1), point (c)					
378	(c) they make a substantial modification to the high-risk AI system.	*(c) they make a substantial modification to the high-risk AI system.*	*deleted*		
Article 28(2)					
379	*2. Where the circumstances*	*2. Where the circumstances*		**Commission's version with**	It is reasonable that the deployer of a foundational

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	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.	*referred to in paragraph 1, point ~~(b) or (c).~~(a) to (ba) occur, the provider that initially placed the ~~high-risk~~ AI system on the market or put it into service shall no longer be considered a provider of that specific AI system for the purposes of this Regulation. This former provider shall provide the new provider with the technical documentation and all other relevant and reasonably expected information capabilities of the AI system, technical access or other assistance based on the generally acknowledged state of the art that are required for the fulfilment of the obligations set out in this Regulation.*	*deleted*	**Amendments** 2. Where the circumstances referred to in paragraph 1, point (a) to (ba) occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered a provider of that specific AI system for the purposes of this Regulation. This former provider shall provide the new provider with the technical documentation ~~and all other relevant~~ and reasonably expected information capabilities of the AI system, ~~technical access or other assistance~~ based on the generally acknowledged state of the art that are required for the fulfilment of the obligations set out in this Regulation. ~~This paragraph shall also apply to providers of foundation models as~~	model that puts its trademark on it, or makes a substantial modification to the model (such as determining its purpose) should be in fact considered a provider of that AI system. They, and not the provider of the original foundation model, will have the knowledge and capabilities to comply with the Regulation. However, the obligations placed upon the original provider to allow the *new* provider to comply are excessively burdensome and not matching the purpose they are pursuing. Requiring the provider to *all* relevant technical documentation is an obligation to subject itself to legal uncertainty and inconsistent interpretation. Moreover, it is impossible to determine in advance and exhaustively all of the possible applications of a model. We recommend replacing it with "reasonably expected information" which ensures foreseeability and legal certainty.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		This paragraph shall also apply to providers of foundation models as defined in Article 3 when the foundation model is directly integrated in an high-risk AI system.		~~defined in Article 3 when the foundation model is directly integrated in an high-risk AI system.~~	Striking the requirement of providing *"technical access"* is also an advisable amendment. First, it is unclear what exactly it would entail. Second, it may not be necessary to achieve the requirements of the Regulation. We think that the requirement to provide the technical documentation, in order to empower the new provider to comply, achieves the right balance between allowing the *new provider* to fulfill its obligations and protecting IP and trade secrets as provided by Union law.
Article 28b [SEE APPENDIX I]					
379d		_Appendix I_		_Appendix I_	_Appendix I_
28(c) NEW [SEE APPENDIX I]					
		Appendix I		_Appendix I_	_Appendix I_
TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS	TITLE IV TRANSPARENCY OBLIGATIONS ~~*FOR CERTAIN AI SYSTEMS*~~	*TITLE IV TRANSPARENCY OBLIGATIONS FOR **PROVIDERS AND USERS OF** CERTAIN AI*			

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		SYSTEMS			
Article 52					
Article 52 Transparency obligations for certain AI systems	Article 52 Transparency obligations ~~for certain AI systems~~	*Article 52* **Transparency obligations for providers and users of certain AI systems~~Transparency obligations for certain AI systems~~**			
Article 52					
512	Article 52 Transparency obligations for certain AI systems	*Article 52 Transparency obligations ~~for certain AI systems~~*	*Article 52* **Transparency obligations for providers and users of certain AI systems~~Transparency obligations for certain AI systems~~**		
Article 52(1)					
513	1. Providers shall ensure that AI systems intended to interact with natural persons are designed and	*1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such*	*1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such*	**Commission's version with amendments** 1. Providers shall ensure that AI systems intended to ~~interact~~ **directly**	Increased transparency is always a positive improvement. However, transparency requirements should continue to be underpinned by the proportionality and risk-based approach that are

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	*a way that **the AI system, the provider itself or the user informs the** natural ~~persons are informed~~**person exposed to an AI system** that they are interacting with an AI system **in a timely, clear and intelligible manner**, unless this is obvious from the circumstances and the context of use. **Where appropriate and relevant, this information shall also include which functions are AI enabled, if there is human oversight, and who is responsible for the decision-making process, as well as the existing rights**	*a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the **point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the** circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences**, subject to appropriate safeguards for the rights and freedoms of third parties***, unless those systems are available for the public to report a*	**dialogue** with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. **For the purpose of this provision, "dialogue" is to be intended as an ongoing exchange between the AI system and the user.** This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	at the basis of the AI Act. Overscoping obligations runs the risk of deterring innovation and unnecessarily burdening AI providers, developers, operators. For this reason, we suggest clarifying the exact meaning of "interaction" for the scope of article 52. Interpretations coming from MEPs, including from VP Vestager, have hinted at "chatbots" as the main focus of this provision, whose objective is to make it "crystal clear to users that they are interacting with a machine". It appears that the risk this provision is trying to mitigate is that of a user being confused and not knowing that they are actively conversing with a machine, rather than a human. However, the current choice of words is overly broad: "interaction" could encompass everything, from an ongoing dialogue to a mere notification. The pervasiveness of AI systems is such that requiring a disclosure every single time that a user comes in contact with an AI system would be untenable. Moreover, providing the user with too

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		and processes that, according to Union and national law, allow natural persons or their representatives to object against the application of such systems to them and to seek judicial redress against decisions taken by or harm caused by AI systems, including their right to seek an explanation. *This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.*	*criminal offence.*		much information may be counterproductive and even impede people's experiences. To more appropriately tackle the risk behind this provision, we recommend substituting "interact" with "direct dialogue", and to specify that dialogue is intended as an exchange between the AI system and the user. This will ensure a better alignment with the intended effect and current interpretation of this provision.
Article 52(2)					

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
514	2. Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.	2. Users of an emotion recognition system or a biometric categorisation system **_which is not prohibited pursuant to Article 5_** _shall inform_ **_in a timely, clear and intelligible manner_** _of the operation of the system the natural persons exposed thereto_ **_and obtain their consent prior to the processing of their biometric and other personal data in accordance with Regulation (EU) 2016/679, Regulation (EU) 2016/1725 and Directive (EU) 2016/280, as applicable_**_. This obligation shall not apply to AI_	2. Users of ~~an emotion recognition system or~~ _a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences_**_, subject to appropriate safeguards for the rights and freedoms of third parties_**_._	Maintain Commission's version	**The Commission's version is the appropriate one here.** GDPR and other relevant Regulations continue to apply regularly. The AI Act is supposed to complement existing regulation - not overlap or supersede it. Therefore, there is no need to introduce additional language related to consent and data processing in Article 52, which is supposed to focus on transparency obligations.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.			
514a			*2a. Users of an emotion recognition system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for emotion recognition which are permitted by law to detect, prevent and investigate criminal offences, subject to appropriate safeguards for the rights and*	**Maintain Commission's version**	**For simplicity, the Commission's text is the best approach here**. There is no real need to proliferate provisions by dividing up the requirements for emotion recognition systems and those for biometric categorisation systems, when they are virtually the same.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
			freedoms of third parties.		
Article 52(3), first subparagraph					
515	3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose that the content has been artificially generated or manipulated.	*3. Users of an AI system that generates or manipulates ~~image~~text, audio or ~~video~~visual content that ~~appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful~~would falsely appear to be authentic or truthful and which features depictions of people appearing to say or do things they did not say or do, without their consent ('deep fake'), shall*	*3. Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful ('deep fake'), shall disclose that the content has been artificially generated or manipulated.*	**Maintain Commission's version**	The requirement to name the person who generated a piece of content is excessive, and could raise serious data protection concerns. If the objective is to reduce the sharing of 'deep fakes', a better way to approach this would be to use user prompts e.g. 'This content is AI-generated, and could be misleading. Are you sure you want to share it?' rather than disclosing people's names. A disclosure of personal information of this type would also severely clash with important data protection principles including data minimization. It is important to remember that AI technologies are evolving rapidly, with new techniques and products emerging all the time and the AI Act needs to be flexible to allow best practices to be developed. It is worth noting that the DSA already places a

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		*disclose **in an appropriate, timely, clear and visible manner** that the content has been artificially generated or manipulated**, as well as, whenever possible, the name of the natural or legal person that generated or manipulated it. Disclosure shall mean labelling the content in a way that informs that the content is inauthentic and that is clearly visible for the recipient of that content. To label the content, users shall take into account the generally acknowledged state of the art and relevant***			requirement under Article 35 for platforms to mitigate risks in this area, and it's important that the AI act does not create conflicting or duplicative requirements. It is also worth noting that the working group on the code of conduct for disinformation will be further exploring this issue and will determine if updates to this code will be required. **The Commission text remains the best option here.**

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		harmonised standards and specifications.			
Article 52(3a)					
516	However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU, and subject to appropriate safeguards for the rights and	*3a ~~However, the first subparagraph~~ Paragraph 3 shall not apply where the use ~~is authorised by law to detect, prevent, investigate and prosecute criminal offences or~~ of an AI system that generates or manipulates text, audio or visual content is authorized by law or if it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental*	*However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences or ~~it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU,~~ ~~and~~where the content is part of an evidently creative, satirical, artistic or fictional work or programme subject to*	**Maintain Commission's version**	**The Commission's version is still the best option here** for clarity and simplicity. In the alternative, the **Parliament's version** requires some caveats, specifically it should specify the copyright should be relevant and *"technically feasible"*.

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
	freedoms of third parties.	*Rights of the EU, and subject to appropriate safeguards for the rights and freedoms of third parties.* **_Where the content forms part of an evidently creative, satirical, artistic or fictional cinematographic, video games visuals and analogous work or programme, transparency obligations set out in paragraph 3 are limited to disclosing of the existence of such generated or manipulated content in an appropriate clear and visible manner that does not hamper the display of the work and disclosing the_**	*appropriate safeguards for the rights and freedoms of third parties.*		

	Commission Proposal	EP Mandate	Council Mandate	Meta's Suggestion	Justification
		applicable copyrights, where relevant. It shall also not prevent law enforcement authorities from using AI systems intended to detect deep fakes and prevent, investigate and prosecute criminal offences linked with their use.			
Article 52(3b)					
516a		*3b The information referred to in paragraphs 1 to 3 shall be provided to the natural persons at the latest at the time of the first interaction or exposure. It shall be accessible to vulnerable persons, such as persons with disabilities or children, complete, where relevant and appropriate, with intervention or*			

Appendix
Article 28b Meta suggestion

Preferred Approach		
Original Text (EP)	Meta's Recommendation	

Article 28b
  Obligations of the provider of a foundation model
   1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels.
 	
   2. For the purpose of paragraph 1, the provider of a foundation model shall:
   (a) demonstrate through appropriate design, testing and analysis the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development
   (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation
	~~Article 28b~~
	~~ Obligations of the provider of a foundation model~~
	~~ 1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels.~~
	
	~~ 2. For the purpose of paragraph 1, the provider of a foundation model shall:~~
	~~ (a) demonstrate through appropriate design, testing and analysis the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development~~
	~~ (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation~~
	~~ (c) design and develop the foundation model in order to achieve throughout its lifecycle~~
		Preliminary Comments:
		
		Regardless of the treatment of foundation models, it must be clarified that copyright provisions (in this case, provisions 4b and 4c) should not be addressed in the AI Act. The rules introduced in the AI Act should build upon existing legislation, not duplicate it or clash with it. The matter of copyright obligations is already covered by Directive (EU) 2019/790 of the European Parliament and of the Council. The AI Act should, thus, defer to it. 4b and 4c should be removed from the text. In particular:
		● **28b(4)(b):** The requirement to provide safeguards against the generation of content in breach of Union law is vague, overbroad, and at odds with fundamental EU principles of proportionality and legal certainty. Ensuring that adequate safeguards are in place should be the responsibility of the user of the generative product, since they are the ones that are most familiar with the functionality of the system, the audience it is used by, and its functionalities.
		● **28b(4)(c):** As the EU Directive on Copyright in the DSM (articles 3 and 4) already provides control to rights holders over the use of their protected works for the purposes of training AI, the focus should be to encourage and facilitate

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(c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development;
(d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;
(e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);.
(f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement.
(g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in

appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development;
(d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;
(e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);.
(f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement.
(g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.
When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in

industry collaboration e.g. for the development of workable standards to ensure the effective control of rights. The proposal concerning copyright law in Art. 28b(4) does not go to the specified objectives of the AI Act. It is broad and unworkable, and, moreover, there is already an extensive and robust EU legal framework in place ensuring IP protection.

Recommended Approach:

The Commission was correct in excluding foundation models from the scope of the Act. The AI Act, in its original draft, takes a technology-neutral, risk-based approach. This approach regulates the uses of the technology, rather than the technology itself. As a result, said approach ensures that the regulation is applied proportionately, introducing requirements to ensure protections in high-stakes settings, whilst avoiding hindering innovation in lower-risk areas.

Foundation models are not inherently risky. As with other AI systems, the risks arise dependent on the context in which they are deployed. It is unnecessary, therefore, to introduce requirements for providers of foundation models. Our recommendation is to retain the risk-based, technology-neutral approach of the EU AI Act and reject these additions.

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Annex VIII point C.
  When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;
  3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities
  4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition
  a) comply with the transparency obligations outlined in Article 52 (1),
  b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression,
  c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.
1c An updated registration entry must be

~~*relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;*~~
~~*3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities*~~
~~*4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition*~~
~~*a) comply with the transparency obligations outlined in Article 52 (1),*~~
~~*b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression,*~~
~~*c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.*~~
~~*1c An updated registration entry must be completed immediately following each substantial modification.*~~

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completed immediately following each substantial modification.		

Compromise Approach 1		
Original Text (EP)	Meta's Recommendation	
Article 28b * Obligations of the provider of a foundation model* * 1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels.* * 2. For the purpose of paragraph 1, the*	*Article 28b* * Obligations of the provider of a foundation model* *1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, as a service, as well as other distribution channels."* *This article does not apply to foundation models made available on open source, or similarly permissive licenses that: (i)*	**Preliminary Comments:** Regardless of the treatment of foundation models, it must be clarified that copyright provisions (in this case, provisions 4b and 4c) should not be addressed in the AI Act. The rules introduced in the AI Act should build upon existing legislation, not duplicate it or clash with it. The matter of copyright obligations is already covered by Directive (EU) 2019/790 of the European Parliament and of the Council. The AI Act should, thus, defer to it. 4b and 4c should be removed from the text. In particular: ● **28b(4)(b):** The requirement to provide safeguards against the generation of content in breach of Union law is vague, overbroad, and at odds with fundamental EU principles of proportionality and

Compromise Approach 1

provider of a foundation model shall:
  (a) demonstrate through appropriate design, testing and analysis the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development
  (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation
  (c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development;
  (d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are

provide open access to models; (ii) further the goal of fostering collaboration and innovation; and (iii) permit downstream users to use, reproduce, distribute, copy, create derivative works of, and make modifications to the foundation model.
  2. For the purpose of paragraph 1, the provider of a foundation model shall:
  (a) demonstrate through appropriate design, testing and analysis the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development
  (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation
  (c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development;

legal certainty. Ensuring that adequate safeguards are in place should be the responsibility of the user of the generative product, since they are the ones that are most familiar with the functionality of the system, the audience it is used by, and its functionalities.

- **28b(4)(c):** As the EU Directive on Copyright in the DSM (articles 3 and 4) already provides control to rights holders over the use of their protected works for the purposes of training AI, the focus should be to encourage and facilitate industry collaboration e.g. for the development of workable standards to ensure the effective control of rights. The proposal concerning copyright law in Art. 28b(4) does not go to the specified objectives of the AI Act. It is broad and unworkable, and, moreover, there is already an extensive and robust EU legal framework in place ensuring IP protection.

In addition to the deletion, we are also proposing some options, which ensure alignment with existing legislation and obligations and that article 28b fits well within the EU legislation framework.

Compromise Approach 1:

The AI Act should incentivise approaches that support the EU's goals for fostering AI innovation in Europe. In its original draft form the AI Act includes an exemption for open source AI systems, in recognition of the critical role that open source development plays in driving innovation and delivering economic benefits from new technologies. In the coming years, access to foundation models will play a similarly crucial role in driving AI research, development, innovation and adoption. It is essential, therefore, that the AI Act facilitates widespread access to, and innovation in foundation models.

Compromise Approach 1

published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;
  (e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);.
  (f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,
  (g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.
  When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;
  3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities

  (d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;
  (e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);.
  (f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,
  (g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.
  When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the

To do so, providers of foundation models should be exempt from the requirements of the Act whenever they decide to make their models available under open source or similarly permissive licences. An approach of this type, which can be described as open innovation, would not only allow European researchers, developers, and citizens to benefit from advances in foundation models, it will also contribute to the creation of higher-performing, safer, and more secure foundation models as a broad community are able to test, scrutinise and improve openly available models.

Compromise Approach 1

4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition
a) comply with the transparency obligations outlined in Article 52 (1),
b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression,
c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.
1c An updated registration entry must be completed immediately following each substantial modification.

latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;
3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities
4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition
a) comply with the transparency obligations outlined in Article 52 (1),
~~b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression,~~
~~c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.~~

Compromise Approach 1

Compromise Approach 2

Original Text (EP)	Meta's Recommendation	
Article 28b *Obligations of the provider of a foundation model* *1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels.* *2. For the purpose of paragraph 1, the provider of a foundation model shall:* *(a) demonstrate through appropriate design, testing and analysis the identification, the reduction and mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining*	*Article 28b* *Obligations of the provider of a foundation model* *1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is provided as a standalone model or embedded in an AI system or a product, as a service, as well as other distribution channels."* ***This article does not apply to foundation models made available on open source, or similarly permissive licenses that: (i) provide open access to models; (ii) further the goal of fostering collaboration and innovation; and (iii) permit downstream users to use, reproduce, distribute, copy, create derivative works of, and make modifications to the foundation model.*** *2. For the purpose of paragraph 1, the provider of a foundation model shall:* *(a) demonstrate through appropriate design, testing and analysis the identification, the reduction and*	To reiterate what stated above, copyright provisions (in this case, provisions 4b and 4c) should not be addressed in the AI Act. The rules introduced in the AI Act should build upon existing legislation, not duplicate it or clash with it. The matter of copyright obligations is already covered by Directive (EU) 2019/790 of the European Parliament and of the Council. The AI Act should, thus, defer to it. 4b and 4c should be removed from the text. In particular: ● **28c(4)(b):** The requirement to provide safeguards against the generation of content in breach of Union law is vague, overbroad, and at odds with fundamental EU principles of proportionality and legal certainty. Ensuring that adequate safeguards are in place should be the responsibility of the user of the generative product, since they are the ones that are most familiar with the functionality of the system, the audience it is used by, and its functionalities. ● **28b(4)(c):** As the EU Directive on Copyright in the DSM (articles 3 and 4) already provides control to rights holders over the use of their protected works for the purposes of training AI, the focus should be to encourage and facilitate industry collaboration e.g. for the development of workable standards to ensure the effective control of rights. The proposal concerning copyright law in Art. 28b(4) does not go

Compromise Approach 2

non-mitigable risks after development (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation (c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development; (d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle; (e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream

mitigation of reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law prior and throughout development with appropriate methods such as with the involvement of independent experts, as well as the documentation of remaining non-mitigable risks after development (b) process and incorporate only datasets that are subject to appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation (c) design and develop the foundation model in order to achieve throughout its lifecycle appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development; (d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, whithout prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published. Foundation models shall be designed with capabilities enabling the

to the specified objectives of the AI Act. It is broad and unworkable, and, moreover, there is already an extensive and robust EU legal framework in place ensuring IP protection.

That being said, If the decision is made to introduce some requirements for all foundation models, by virtue of their nature alone, a distinction must be made between providers who make their models available in an open and transparent way, such as under open source or similarly permissive licences; and those that take a closed approach.

In addition, improvements must be made to the current text to ensure that requirements are technically feasible and tailored to their purpose. Requirements applicable to all foundation models might focus on transparency, data governance, technical documentation, and risk assessment, in line with industry best practices, while providers of closed models may be expected to meet additional requirements, so as to provide additional assurance and oversight of those models. These additional measures need not apply to open models, as these models are at the disposal of more downstream developers, who can in turn scrutinise the software, identify and fix potential issues and therefore improve performance, safety, and security.

A tiered regime, as outlined below, will ensure that the AI Act delivers on its dual goals of ensuring protections for EU citizens, whilst fostering innovation in AI.

Our suggested approach is that a tiered regime is applied depending on whether the foundation model is released under an open source, or similarly permissive license, or else.

If the foundation model is released under a closed system, then **the Parliament text proposed under 28b** would apply

Compromise Approach 2

providers to comply with their obligations pursuant to Articles 16 and 28(1);.
* (f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,*
* (g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.*
*   When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;*
*   3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities*
*   4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition*
* a) comply with the transparency obligations outlined in Article 52 (1),*
*   b) train, and where applicable, design and develop the foundation model in such a way*

measurement and logging of the consumption of energy and resources, and, where technically feasible, other environmental impact the deployment and use of the systems may have over their entire lifecycle;
*   (e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);.*
*   (f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,*
*   (g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.*
*   When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;*
*   3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities*

as it is (see **amendment 379d** above).

If the foundation model is released under an open **source model,** on the other hand, a differentiated regime would apply. This regime is represented by our proposed **article 28c,** which relies on the **Parliament's proposed 28b** as a starting point, but is amended to better adapt to the nature of open models and to continue to maintain that **risk-based approach** that is core to the Act.

Specifics:

- **28c(2)(a):** It is reasonable to expect the provider of a foundation model to do an initial risk identification and mitigation, to document this process and to be transparent about risks identified and mitigated. For models provided on open source and similarly permissive licences, which by their nature are minimally restrictive with regards to downstream uses, it is not possible to complete comprehensive testing and analysis for risks, and this responsibility must sit with downstream users.
- **28c(2)(b):** Requirements should be sufficiently flexible so as to allow bias identification and mitigation to happen at the most appropriate stage of development, whether that is at the dataset or model level. The proposed amendment ensures that examining the suitability of data sources is one of numerous tools that providers can use to achieve optimal fairness outcomes for their models.
- **28c(2)(c):** It is reasonable to expect the provider of a foundation model to take steps at the design and development stage to ensure performance, safety and security, but the other elements are more closely tied to specific use cases, and are therefore best addressed and overseen by downstream users.
- **28c(2)(d):** Improving the efficiency of foundation

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as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression, *c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.* *1c An updated registration entry must be completed immediately following each substantial modification.*	*4. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition* *a) comply with the transparency obligations outlined in Article 52 (1),* ~~*b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression,*~~ ~~*c) without prejudice to Union or national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.*~~	models is an important priority. However, the requirement for logging capabilities across the entire lifecycle of a foundation model are unrealistic and infeasible. Each actor along the AI value chain should be encouraged to measure and take steps to reduce the environmental impact of their stage of the model's life cycle. ● **28c(2)(g):** The proposed amendment would ensure a high standard of quality, whilst permitting providers who make their models available under open source and similarly permissive licences a certain degree of flexibility. This, in turn, would promote innovation and investments in making technology safer enforcement.
	28c [NEW] **OBLIGATIONS OF THE PROVIDER OF A FOUNDATION MODEL UNDER AN OPEN SOURCE OR SIMILARLY PERMISSIVE LICENCE** 1. A provider of a foundation model shall, prior to making it available on the market or putting it into service, ensure that it is compliant with the requirements set out in this Article, regardless of whether it is	

Compromise Approach 2		
	provided as a standalone model or embedded in an AI system or a product, or provided under free and open source licences, as a service, as well as other distribution channels. 2. For the purpose of paragraph 1, the provider of a foundation model shall: a) Conduct, and provide documentation of an analysis to identify, and where appropriate, mitigate reasonably foreseeable risks to health, safety, fundamental rights, the environment and democracy and the rule of law, as well as the documentation of remaining non-mitigable risks after development. b) Adopt appropriate data governance measures for foundation models, in particular measures to examine the suitability of the data sources and possible biases and appropriate mitigation. Or, if it is more appropriate, effective, or technically feasible, conduct analysis on the foundation model's outputs to identify, and mitigate possible biases. c) design and develop the foundation model in order to achieve ~~throughout its lifecycle~~ appropriate levels of performance, ~~predictability, interpretability, corrigibility,~~ safety and cybersecurity assessed through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during	

Compromise Approach 2		
	conceptualisation, design, and development;	

(d) design and develop the foundation model, making use of applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system, without prejudice to relevant existing Union and national law. This obligation shall not apply before the standards referred to in Article 40 are published.
(e) draw up extensive technical documentation and intelligible instructions for use, in order to enable the downstream providers to comply with their obligations pursuant to Articles 16 and 28(1);
(f) establish a quality management system to ensure and document compliance with this Article, with the possibility to experiment in fulfilling this requirement,
(g) register that foundation model in the EU database referred to in Article 60, in accordance with the instructions outlined in Annex VIII point C.

When fulfilling those requirements, the generally acknowledged state of the art shall be taken into account, ~~including as reflected in relevant harmonised standards or common specifications, as well as the latest assessment and measurement methods, reflected in particular in benchmarking guidance and capabilities referred to in Article 58a;~~

Compromise Approach 2		
	3. Providers of foundation models shall, for a period ending 10 years after their foundation models have been placed on the market or put into service, keep the technical documentation referred to in paragraph 2(e) at the disposal of the national competent authorities. Providers of foundation models used in AI systems specifically intended to generate, with varying levels of autonomy, content such as complex text, images, audio, or video ("generative AI") and providers who specialise a foundation model into a generative AI system, shall in addition provide relevant materials to enable downstream users and providers to comply with the transparency obligations outlined in Article 52 (1). b) train, and where applicable, design and develop the foundation model in such a way as to ensure adequate safeguards against the generation of content in breach of Union law in line with the generally-acknowledged state of the art, and without prejudice to fundamental rights, including the freedom of expression, c) without prejudice to national or Union legislation on copyright, document and make publicly available a sufficiently detailed summary of the use of training data protected under copyright law.	