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## **Key messages for the AI Act trilogues**

Artificial intelligence systems provide game-changing tools for companies, consumers, and public authorities to reap the benefits of digitalisation. To keep up with the global AI race, Europe needs significantly more investments in the innovative development and deployment of AI across all sectors of society. This applies also to European manufacturing industries where AI is a key factor in boosting productivity and sustainability by unlocking the promised value of connected products and industrial data.

We support the aim of developing and deploying AI in a trustworthy and ethical manner. We also agree that the EU has a role in ensuring that AI systems offered in the European Single Market are human centric and robust and that their potential risks are addressed and where possible mitigated. The EU should do this by laying out clearly defined rules that foster legal certainty and establish unambiguous sharing of responsibilities up and down the AI value chain.

The proposal for an AI Act, although welcome, is not without its shortcomings, however. As the Act enters the trilogues, we are concerned about several aspects of the text. There is a danger that the Regulation's key definitions and provisions will turn out to be overly vague and its scope too broad and prescriptive for the purposes of a horizontal legislation that intends to be risk-based and future-proof.

We urge the EU co-legislators to make the necessary course correction and adopt a more balanced and innovation-friendly approach when finalising the Act.

### **1 Definitions – Article 3**

#### **Artificial intelligence system**

- 'AI system' should mean a system that is designed to operate with elements of autonomy and produces system-generated outputs, as proposed by the Council. The definition should therefore not comprise the use of deterministic, easily explainable logic- and knowledge-based approaches and be limited as a rule to machine learning.
- It is crucial to limit the scope of the Regulation to cover only systems that are de facto AI, rather than extend it to cover systems and software far less complex and autonomous such as those often deployed in machinery and their safety components that simply follow rules set by humans on an automated basis and which are already covered by the existing product safety rules.
- Autonomy, however, should not be mistaken with automation, as these concepts are distinct. This distinction should be clarified in the relevant recitals. Automation simply means that a machine will execute a deterministic process. An autonomous system, on the other hand, learns and adapts to dynamic environments, and evolves as the environment around it changes.

#### **Significant risk**

- It is unclear where exactly the threshold between 'risk' and 'significant risk' lies and what the relationship between 'significant risk' and 'high risk' is.

- We strongly encourage legislators to properly assess this definition during trilogues, with the aim to establish a clear understanding of what the multiple types of risk in the AI Act are, and their differences.
- If this definition would have to stay in the text, we would propose to align it with the existing Market Surveillance and Product Compliance Regulation and thereby changing 'significant risk' to 'serious risk' and adding in the wording: "based on a risk assessment and taking into account the normal and foreseeable use of the product".

### **Safety component of a product or system**

- We ask to align this definition with the one found in the Machinery Regulation as companies have already aligned their safety solutions and protocols accordingly.

## **2 Classification rules for high-risk AI systems – Article 6**

- The risk-based approach to regulating AI is justified but requires special attention to legal clarity. Different actors in the AI value chain need to know with high certainty whether a provision or deployment of an AI system in a particular setting is considered high risk, presently and in the foreseeable future, and whether it needs to comply with high-risk requirements.
- Clarity is instrumental in facilitating the required European investments in AI solutions throughout society, especially in industries. AI solutions will play a key role in driving improvements in energy and material efficiency and hence better productivity throughout the industries.
- Only when a significant risk of harm to health and safety is identified in specific deployment or use of an AI system, should the said system be classified as high risk. Therefore, a more nuanced approach to classification is preferable to one with no room for justified exceptions.
- The classification rules, as they are currently formulated by the Council and the Parliament, establish two paths that both lead an AI system to fall under high-risk requirements: (1) product safety legislation (listed in Annex II), and (2) other high-risk areas (listed in Annex III). With this mind, we note the following:

### 1. Product safety legislation

- The Parliament's formulation of Article 6(1) is preferable: it offers two conditions (points a + b) that a high-risk system needs to fulfil, as was originally proposed by the Commission, and modifies the point b so that a third-party conformity assessment needs to be related to risks for health and safety.
- However, we urge the final text to acknowledge that in industrial applications, the use of an AI safety component does not necessarily critically affect product safety, as other reliable non-AI safety components too may be in place to ensure the sufficient safety of the product. Therefore, AI should only be considered high risk if the AI system is *an essential safety component* by virtue of, for example, being the only safety component in the product.

### 2. High-risk areas

- We welcome the Council's and the Parliament's efforts to adhere to the risk-based approach of the Regulation by introducing clarity to situations where an AI system falling under the critical areas referred to in Annex III nevertheless does not de facto pose significant risks and therefore cannot be classified as high risk.
- We recommend combining the approaches of the Council and the Parliament so that AI systems which (i) produce purely accessory outputs, or (ii) which do not pose significant risks to the health, safety or fundamental rights of natural persons, are not categorized as high risk despite being used in one of the critical areas of Annex III.
- The providers should be able to self-assess under which risk category their AI systems classify, based on the guidelines produced by the Commission prior to the entry into application of the Regulation.
- The Parliament's Articles 6(3) and 6(4) are not advisable since they would needlessly limit the providers' self-assessment by introducing a notification procedure and thereby causing legal uncertainty and creating an unlevel playing field between Member States.
- Lastly, we think the requirement in the Parliament's Article 6(2) relating to the environment is unnecessary, as environmental impact should be dealt with in other regulation, and not in the AI Act.

### **3 General-purpose AI and foundation models**

- General-purpose AI (GPAI) refers to a large and diverse category of purpose-neutral AI systems, some of which are built upon so-called foundation models. A GPAI system can be deployed in numerous use-cases with varying risk levels either as a standalone system or as a component of a narrower AI system.
- It can be foreseen that the development and uptake of AI in many industries, including manufacturing, is increasingly driven by GPAI, or more precisely AI systems based on GPAI systems and models. This being the case, it is crucial to find an approach to regulating GPAI systems and different entities in their value chains that is (1) unambiguous (creates no legal uncertainty), (2) balanced (actors in the AI value chain are responsible for things they have real possibilities and means to influence), and (3) proportionate (adheres to the risk-based approach).
- As a rule, and as proposed by the Council in Article 4a, GPAI systems should comply with the high-risk requirements only when they are intentionally provided or deployed as high-risk AI systems or components thereof. When this high-risk provider is other than the original provider of the GPAI system, the GPAI provider should be obliged to assist, to the extent that is reasonable, the downstream provider in complying with its obligations to ensure the AI system meets the high-risk requirements, unless the GPAI provider has explicitly forbidden all high-risk uses of its system or the system has been provided under free and open-source licenses.
- When GPAI systems or parts thereof are used to develop low-risk applications by third parties, the original provider should have some limited responsibility, in particular with

regard to the disclosure of relevant technical documentation, unless GPAI systems or their components have been provided under free and open-source licenses.

- The need for ex ante requirements – other than those regarding high-risk deployment mentioned above – for GPAI systems, including underlying foundation models, should be carefully assessed together with their impacts on innovation and competitiveness of European companies. In general, any such requirements, should they be deemed necessary, ought to be future-proof and technology-neutral. Therefore, it is not advisable to treat foundation models separately from other technical approaches to GPAI, as the Parliament does, but to create a common regulatory framework for all GPAI systems and underlying models.
- If general ex ante requirements are introduced, they should not apply to GPAI systems and underlying models that are offered under free and open-source licenses, contrary to the Parliament’s proposal, as this would impede their development and provision in the EU and consequently hold back the uptake of AI in European industries.
- Given that foundation models are still in their infancy, the requirements imposed on them by the Parliament in Article 28b are in our view unclear, disproportionate, and onerous.

#### **4 AI regulatory sandboxes – Article 53**

- Regulatory sandboxes are essential in assisting AI developers, especially SMEs and startups, in complying with the requirements of the Regulation.
- To ensure a level playing field between AI providers regardless of their place of establishment in the EU, we favor mandating, in line with the Parliament’s position, each Member State to establish at least one Regulatory sandbox with sufficient resources and national coverage and to have it operational prior to the entry into application of the Regulation.
- AI systems that undergo the sandboxing process should exit it with the presumption of conformity with the specific requirements of the Regulation that were assessed in the sandbox.

#### **5 AI Office – Article 56**

- The proposition by the Parliament to establish the AI Office, a weightier version of the Commission-proposed European AI Board, signals that even the lawmakers consider the Regulation burdensome to implement and therefore in need of additional support from the EU officials to Member States.
- Although it is sensible to assist national authorities in the implementation, it cannot compensate for the apparent lack of supervisory expertise in Member States, an issue that is potentially exacerbated by the high level of complexity and ambiguity of the AI Act.

#### **6 Entry into force and application – Article 85**

- To give the actors in the AI value chain enough time to adapt to the new rules, we recommend that the Regulation should enter into application no earlier than from 36 months after the entry into force, as proposed by the Council.

- Considering that this is a completely new regulation and that there are no existing AI standards, a transition period of less than 36 months would be inadequate, to say the least. Negative consequences could range from increased costs for manufacturers to carry out conformity assessments to the industry not being able to place products on the market in a timely manner, with effects for all concerned – from the manufacturers to the users and ultimately the consumers.

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