

Agoria Position paper : European Commission proposal for a regulation on Artificial Intelligence

Agoria is the Belgian federation for the technology industry. We are paving the way for all technology-inspired companies in Belgium pursuing progress internationally through the development or application of innovations and which, together, represent some 300.000 employees. We are proud that more than 1.900 member companies trust in the three pillars of our services: consulting, business development and the creation of an optimal business environment.

Agoria and its members **welcome** the European Commission's proposal for a regulation on artificial intelligence ("AI"). The proposal can enhance trust in AI applications, by establishing a clear and stable legal framework that creates the investment climate that is necessary to strengthen this promising industry. Agoria submits the following comments and suggestions to achieve those objectives.

First, Agoria suggests **refining the scope**, by adjusting the proposed definition of AI systems, the classification of identified high-risk AI applications and the allocation of roles. The scope of the regulation is essential, requiring clear definitions that are easily interpretable and applicable. The relevant stakeholders must be able to assess whether their systems and applications are subject to the regulation and which rules apply.

Currently, the *definition of AI system* seems very broad, and could cover most IT systems. Therefore, providers need guidance to help them to determine whether a system is an AI system or a traditional IT system. It should be considered that AI is a subject which is being heavily researched and under constant evolution, and new techniques are being developed at a fast pace. Also, there is a risk that AI technologies will not be used for high-risk applications, merely to avoid the application of this regulation.

In case of an AI system, there is a similar issue when *identifying the risk level* and therefore guidance on assessing the risk level of AI systems is required. The list of high-risk AI systems in Annex III is a good attempt to identify a number of use cases which present a specific risk. However, AI systems that are currently available rarely have the exact same application as described. In such case, it is unclear what the provider should do, if and to what extent its application may be considered a high-risk application. Something that could bring clarity are clear criteria and a process on evaluating and classifying use cases.

Also, the allocation of *roles and related responsibilities* of these stakeholders should be straightforward and easy to apply, considering that AI applications often entail complex supply chains. This allocation of roles is crucial from a liability point of view as well, since the proposed regulation focuses on the use of the AI applications rather than on the systems.

For example, a company develops an AI application in the medical field and sells it to another big company who integrates this into one of their software packages. This software package can be used by medical professionals, and directly by end users. In this specific case, the role allocation seems unclear to us. Due to the nature of the digital product supply chain, there are a multitude of different possibilities which go beyond the 'provider' and 'user' approach. A lot more clarification is needed here.

Second, Agoria proposes to **clarify the possibilities to amend the annexes** to the regulation. Additional clarification is required as to the relevant criteria, consultation procedures and

implementation process. Modifications to the regulation and in particular to the scope would compromise legal certainty and predictability for the stakeholders, as well as their application of the regulation. Therefore, modifications to the regulation would require adequate consideration and consultation, which should be duly specified in the draft. It is vital that industry stakeholders are involved in the process of modification in order to provide legal clarity and bring trust.

Third, the **timeline** will be important for the providers, for the application of both the regulation in its initial version and the modifications made afterwards.

The proposal specifies that AI systems should *comply with the regulation* when “placed on the market” or “put into service”. This concept is already well-established and documented in existing legislation relating to physical products, but for digital products this concept is quite new. As digital systems often undergo multiple iterations and developments before they are considered to be fully implemented and ready to release, clarification is needed on when the AI system should be compliant. If, for example, compliance should already be ensured when a proof of concept is delivered to a client, this would significantly increase the costs of developing an AI business case while at that point there is no certainty the application will actually be purchased by the client.

The *application of modifications* to the regulation is equally important and even more delicate. In that case, the modifications will impact AI systems that are already on the market and are being used, requiring sufficient time for providers to implement these rules. In case of changes, a transition period of minimum two years should be foreseen to ensure that industry has time to ensure their solutions are compliant with the amended regulation.

Fourth, Agoria suggests focusing on the **intended uses** of the AI applications, **as determined by the providers**. The concept of “reasonably foreseeable misuse” will undoubtedly make the application of the regulation more difficult for providers and result in discussions between the stakeholders. Also, the providers should not be liable in case of the users’ misuse of the AI application, especially if such misuse is intentional or if the provider has no means of avoiding this risk.

Fifth, as regards the **support for innovation**, Agoria notes that the proposal recognized the administrative and financial impact it has on providers of AI systems. Agoria expects that the proposed support mechanisms **will not suffice** to ensure that our European companies can continue to innovate. In general, most SMEs believe that this regulation will put them at a huge disadvantage, as their size and limited resources will make it difficult to comply with this regulation. This matter should get more attention, as often it is the small-scale providers that drive AI innovation and build the applications needed to improve the quality of our lives.

Regarding *regulatory sandboxes*, it is positive that the Commission urges the Member States to take action, although this should be further formalized. Agoria considers that regulatory sandboxes can only foster innovation if they are supported by adequate incentives and budgets.

On the *measures for small scale providers and users*, Agoria supports the proposal although we consider that these measures need to be extended. While these small-scale providers and users have priority access to legal sandboxes, participating in them will require a huge time investment from their side and Agoria is of the opinion they should be financially encouraged to participate. It is positive that there will be a reduction of the cost on third-party conformity assessment, although this should be further extended to specific funding for companies that undergo a self-assessment procedure. In Belgium we see that start-ups, scale-ups and SME’s develop many of the most innovative AI applications. We think that this regulation will put them at a competitive disadvantage compared to bigger companies that already have a lot of experience with compliance mechanisms.

As a final point, the European Union should consider that this regulation will have a considerable **impact on its place in the AI world**. A negative impact on AI applications that could have a positive

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impact on our society should be avoided at all costs. If the regulation hinders innovation and deters investments in the EU markets, the providers will offer their applications elsewhere.

The aim to build trust in AI is crucial and so is mitigating the potential negative impact of AI, while this should not prevent the EU from reaping all the positive benefits that AI can bring to our society.