

Truly Risk-Based Regulation of Artificial Intelligence

How to Implement the EU's AI Act

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Standalone Summary*

1. Why the AI Act is not based on a truly risk-based approach

The recently adopted Artificial Intelligence Act (AI Act) of the European Union (EU) claims to be based on a risk-based approach to avoid over-regulation and to respect the principle of legislative proportionality. Recital (26) AI Act points out that: “In order to introduce a **proportionate** and **effective** set of binding rules for AI systems, a clearly defined **risk-based approach** should be followed. That approach should **tailor the type and content** of such rules to the **intensity** and **scope of the risks** that AI systems can generate.”

This paper argues that risk-based regulation is indeed the right approach to AI regulation. At the same time, however, the paper shows that important provisions of the AI Act do not follow a truly risk-based approach – contrary to the claims of the European Commission and the co-legislators.

- **No risk-benefit analysis:** The AI Act does not consider the potential benefits of AI systems, such as advancing scientific discovery, alongside the risks they pose. Instead, the Act focuses primarily on risks. This approach ignores that a consistent application of the risk-based approach requires thorough consideration of, not only the negative consequences, but also the positive contributions that AI brings to individuals and society. After all, “risk” is something we take in the name of benefit; we don’t typically choose to be harmed. Instead, we, as a society, choose to take certain risks in the name of current and potential societal gains.
- **Limited reliance on empirical evidence:** Moreover, the paper shows that the supposedly “risk-based” nature of the Act is neither based on practical evidence nor justified by externally verifiable criteria, but is largely the result of a political compromise.
- **Pre-defined, closed risk categories:** Instead of providing a risk classification on a case-by-case basis, the AI Act uses a pre-defined list of typical high-risk applications. This leads to over-regulation where, for instance, an AI system falls into one of the eight categories listed in Annex III, but in reality does not pose a significant risk of harm. At the same time, such an approach creates a sharp rift between this category and other lower-risk categories that are largely unregulated.
- **Regulation of GPAI models:** The specific obligations for GPAI are inconsistent with the risk-based approach, in that they regulate a certain technology instead of concrete risks. Moreover, the newly introduced category of a “systemic risk” with its floating-point

* The full version of the paper is available for download at: <https://ssrn.com/abstract=4870387>.

operations per second (FLOPs) threshold is not based on empirical evidence but the result of a political compromise.

- **Overly broad AI definition:** The AI Act applies not only to machine learning, but also to logic- and knowledge-based approaches. As a result, even deterministic software systems used in high-risk sectors are subject to the highest requirements, although these systems are safer and easier to control than unpredictable systems based on machine learning.
- **Double regulatory burdens:** The AI Act does not replace existing EU laws but applies concurrently to it. Such a horizontal approach leads in many areas to legal uncertainty, different interpretations, contradictions and, ultimately, to double regulatory burdens – contrary to the idea of truly risk-based regulation.
- **Overlap of enforcement tools:** Since the AI Act applies in addition to existing EU laws, it is likely that the same use of an AI system will be subject to different regulatory authorities in one and the same Member State, increasing legal uncertainty and compliance costs.

2. Recommendations on how to implement the AI Act

Although key provisions of the AI Act do not reflect a truly risk-based approach, the Regulation provides for sufficient tools to interpret, specify, and even amend it in line with a genuine risk-based approach, such as guidelines, delegated and implementing acts of the European Commission, codes of practice, and harmonized standards.

When implementing the AI Act, both the European Commission and the Member States must respect the choice of the European legislator to follow a risk-based approach. This follows both from the preparatory work and from the *ratio legis* as laid down in recital (26) AI Act. Moreover, the principle of (legislative) proportionality to avoid over-regulation is also enshrined in Art. 5 TEU.

For this, the following aspects should be taken into account:

- **Risk-benefit analysis and evidence-based High-Risk Categories:** The European Commission has power to amend, modify or remove use-cases for high-risk AI systems in Annex III (Art. 7(1) and 7(3) AI Act) and to modify or add new conditions under which Annex III high-risk AI systems shall not be considered to be high-risk according to Art. 6(3) AI Act (Art. 6(6)-(7) AI Act). In doing so, the Commission should explicitly weigh the economic and social benefits of AI systems against the risks, based on sufficient empirical evidence.
- **Regulation of GPAI models:** The European Commission can amend the thresholds for classifying GPAI models as “systemic” risk (Art. 51(3) and Art. 52(4) AI Act). Accordingly, the Commission has the opportunity to use real-world evidence to set and define the systemic risk threshold by going beyond FLOPs and adding or replacing them with new benchmarks. In addition, it will be of paramount importance that the codes of practice clearly specify which systemic risks GPAI model providers must assess and mitigate pursuant to Art. 55(1) AI Act.
- **Overly broad AI definition:** Proper risk-based implementation can also mitigate the overly broad definition of AI, because many of the requirements in Art. 8-15 AI Act are worded broadly enough to be applied in a manner that takes into account the fact that AI systems pose different risks due to their different levels of autonomy and adaptability.

- **Double regulatory burdens and overlap of enforcement structures:** The European Commission should conduct an analysis to identify double regulatory burdens and an overlap of enforcement structure. Based on this research, guidelines could then be rolled out to clarify the relationship between the AI Act and other EU laws as well as the question whether a particular governance body is the lead authority.
- **Revision of sector-specific EU Laws:** The legislator should revise sector-specific EU law, in order to clarify regulatory overlap, streamline definitions and risk assessment procedures, and clarify which governance body competent is the lead authority and how the different bodies should cooperate with each other.

3. Regulating AI outside the EU: Lessons from the AI Act

Lawmakers around the world are looking at the AI Act to determine whether they should follow the European Union’s lead and adopt similar laws to regulate AI systems. This is the so-called (*de iure*) “Brussels Effect”. This paper argues that it is unlikely that the AI Act will unfold such an effect. Moreover, in light of the lessons the AI Act can teach lawmakers around the world, such an effect would also be undesirable.

Why the AI Act *won’t* trigger a Brussels Effect: The paper argues that it is unlikely that countries outside the EU will simply copy and paste the AI Act, because

- AI does not present a single policy problem (unlike the GDPR) but rather a set of loosely connected problems,
- There is little international consensus on *who* and *what* should be regulated, and *how*.
- The AI Act does not establish a comprehensive legal framework that can be adopted *tel quell*, but interacts instead in a very complex way with a rather sophisticated system of existing EU laws.

Why the AI Act *shouldn’t* trigger a Brussels Effect: There are also important reasons as to why a *de iure* Brussels effect of the AI Act is not desirable, because

- Different countries and citizens affected differently by AI due to the respective economic, social, legal and political situation,
- AI-specific regulation is still in its early stages, and it is unclear what the social and economic consequences of the AI Act will be,
- The existence of different AI regulations in different countries can stimulate experimentation and innovation in regulation through trial and error,
- The risk-based approach of the AI Act is ill-suited to protect human rights.

Finally, legislators around the world should take into account that key provisions of the AI Act do not follow a truly risk-based approach, particularly with respect to proper risk-*benefit* analysis, limited reliance on empirical evidence, pre-defined and closed risk categories, systemic risks of GPAI models, the overly broad definition of AI, double regulatory burdens, and overlapping enforcement structures.

It is also, and above all, for these reasons that regulators outside the EU should not blindly follow the European Union’s approach.