

Preserving the Integrity of the AI Act: Why Annex I Must Remain Unchanged

We, organisations and individuals representing stakeholders in AI safety, standards, and governance welcome the co-legislators' efforts to simplify the AI Act through the AI Omnibus. However, we are concerned that certain amendments tabled by the joint IMCO-LIBE Committee could undermine the AI Act's overall regulatory architecture and its core policy objectives.

In particular, Annex I, Section A of the AI Act must remain unchanged. Proposed amendments to remove or shift [New Legislative Framework \(NLF\)](#) legislation listed in Section A would weaken the horizontal architecture of the AI Act and exclude a broad range of AI systems from its direct scope. We therefore **call on the co-legislators to preserve the current structure of Annex I and address potential overlaps with sectoral legislation through guidance** rather than structural changes to the AI Act.

The Risk: Hollowing Out the AI Act's Core

The proposal to shift NLF legislation from Annex I, Section A, to Annex I, Section B (e.g., IMCO-LIBE amendments No. 435-441), or to delete Annex I Section A entirely (e.g., IMCO-LIBE amendments No. 108 and 183), would effectively exclude a wide range of industrial and consumer AI systems from the direct scope of the AI Act, potentially undermining European sovereignty and safeguards designed to protect EU consumers. This is not a technical adjustment; it is a structural rollback with significant consequences, including:

- AI-related risks embedded in sectoral EU product legislation would remain unaddressed, negatively impacting the safety of consumers.
- A fragmented and unpredictable regulatory landscape would emerge across the EU, running counter to the simplification objective of the AI Omnibus and ultimately increasing, rather than reducing, regulatory complexity.
- Providers and regulators would face increased legal uncertainty, not reduced complexity.
- The EU would forfeit a historic opportunity to establish global leadership in AI governance.

The Argument for Removal of Annex I, Section A Does Not Hold

From an AI-safety perspective, the argument put forward by proponents of these changes, namely that AI risks are already sufficiently covered by sectoral legislation, does not hold. The vast majority of NLF product legislation, such as radio equipment, toys, or pressure equipment, does not contain specific AI requirements.

The Medical Devices Regulation and the Machinery Regulation include certain software/AI-related provisions, but even these laws are not as comprehensive as the horizontal requirements of the AI Act, particularly regarding robustness, data governance and transparency. For example, the Machinery Regulation does not establish clear obligations for lifecycle monitoring of AI system performance, and the Medical Devices Regulation does not include explicit transparency requirements comparable to those set out in the AI Act.

The Hidden Consequences of a Section B Shift

A shift of NLF frameworks into Annex I, Section B (e.g., by merging Section A into B) would also mean that the AI Act's requirements would no longer apply directly. Instead, the EU legislator would have to only "take into account" the AI Act requirements if they were to adopt delegated or implementing acts in sectoral legislation (cf. Articles 102-109 AI Act). Importantly, **such delegated or implementing acts would require additional regulatory processes rather than simplification, running counter**

to the streamlining objectives of the AI Omnibus while prolonging legal uncertainty for economic operators.

In other words, **there would be no obligation to introduce binding AI rules into sectoral legislation**, nor would their content, timing or structure be clearly defined in the AI Act. Risks stemming from high-risk AI systems would thus remain largely unaddressed if the proposed shift to Section B were realised. The core objective and key added value of the AI Act, **namely, to establish a harmonised and risk-based regulatory framework for AI systems, would be significantly weakened.**

Hence, contrary to the arguments put forward, shifting Annex I, Section A sectors out of the AI Act's scope would lead to an increasingly fragmented and unpredictable landscape at a time when EU requirements for AI safety and trustworthiness are highly in demand by consumers and industry. This could result in sectoral AI requirements emerging at different speeds, with some sectors adopting measures earlier than others, thereby creating uneven compliance expectations across the Single Market. With AI systems and AI safety components expected to become integral parts of industrial value chains in the coming decades, such fragmentation would set a precedent that we fear would be highly detrimental to regulatory coherence and market certainty.

Our Ask

We call on the European Parliament and Member States **to maintain the horizontal approach of the AI Act with the AI Omnibus.** Simplification must not come at the cost of protection.

We recognise that overlaps and inconsistencies exist between the AI Act and NLF legislation. **However, in our view, the solution is to provide legal clarity through timely interpretative guidance from the European Commission** (e.g., joint implementation notes with sectoral regulators, horizontal guidance documents clarifying the interaction between the AI Act and NLF frameworks, detailed Q&A for industry and authorities, and practical templates for integrated conformity assessments) **rather than removing entire categories of EU product legislation from the AI Act's scope and thereby leaving important product areas insufficiently regulated concerning AI risks.**

Signatories

Organisations



Pour Demain is an independent think tank working towards the responsible development and deployment of general purpose AI in the EU and beyond. Our work, spanning fora such as the European Union, Council of Europe, OECD, G7, as well as governments at the national and regional level, has contributed to the emergence of frontier AI governance. Building bridges between science and decision-makers, we seek a safe and secure future.



TIC Council is the international trade association representing the Testing, Inspection, and Certification (TIC) industry, with more than 100 member companies worldwide. Its members provide independent conformity assessment services that help ensure the safety, quality, and compliance of products, services, and systems across global markets. TIC Council members are expected to play a key role in the practical enforcement of the AI Act. Many of these organizations will act as Notified Bodies (NBs).



The Future Society (TFS) is an independent nonprofit organization with a mission to align AI through better governance. TFS works to ensure that AI poses no severe risks and promotes security, sovereignty, and fundamental freedoms. TFS's focus is on the most powerful AI, including advanced efforts toward autonomous agents, Artificial General Intelligence, or superintelligence.



TÜV AI.Lab was founded in 2023 as an independent joint venture by the TÜV companies TÜV SÜD, TÜV Rheinland, TÜV NORD, TÜV Hessen and TÜV Thüringen. The TÜV AI.Lab aims to translate the regulatory requirements for AI into practice and make Europe a hotspot for safe and trustworthy AI. To this end, it develops quantifiable conformity criteria and suitable test methods for AI. The AI.Lab also actively supports the development of standards and norms for AI systems.

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