11 March 2026

Open Letter: No fragmentation of EU AI Act – Preserve the horizontal approach

We, the undersigned organisations, would like to strongly warn against current proposals in the context of the **Digital Omnibus on AI** (2025/0359(COD)) that would abandon the horizontal regulatory approach of the European AI Act. Moving high-risk products to the so-called **Annex I-B** would call into question a central foundation of European AI legislation.

Such a step would not lead to the intended simplification. Instead, it risks **regulatory fragmentation, new legal uncertainty and, in the long term, higher burdens for companies operating in the European Single Market**.

A coherent horizontal regulatory approach is crucial for three reasons:

1. Sector-specific legislation would increase bureaucracy for businesses

The current proposals aim to simplify AI legislation. In practice, however, the opposite would occur. If key product areas were removed from the horizontal scope of the AI Act, essential AI safety requirements would first have to be newly developed across numerous sector-specific directives and regulations – without any guarantee as to whether and when this would actually happen. Diverging requirements, timelines and assessment procedures could emerge. For companies, this would mean significantly more bureaucracy, higher compliance costs and reduced legal certainty.

2. The safety of AI systems requires binding, clear and uniform standards

AI is increasingly being deployed in safety-critical areas – for example in medical diagnostics, industrial machinery, connected consumer products and automated decision-making processes. Faulty or manipulated systems can have immediate consequences for health, safety and fundamental rights. The AI Act establishes for the first time a common European safety framework for high-risk AI systems, including requirements on robustness, data quality, transparency, risk management and human oversight. The large majority of EU product legislation – for example on radio equipment, toys or pressure equipment – contains no specific AI requirements. Even where software aspects are addressed (particularly for medical devices and machinery), key AI risks such as robustness, data governance and transparency remain insufficiently covered.

3. Uniform rules strengthen Europe's competitiveness and global supply chains

Europe can only compete globally in the race for AI technologies if the European Single Market provides for clear and consistent regulatory conditions. A system with numerous sector-specific AI rules would slow down innovation, increase regulatory complexity and place particular burdens on start-ups and SMEs. Instead of a clear framework, a fragmented regulatory landscape would emerge. Amidst competition with major AI ecosystems such as the United States and China, it is crucial that Europe establishes scalable and harmonised requirements. Only in this way can these rules shape international practice – an essential factor for globally integrated supply chains. A robust and unified European AI Act is the best foundation for strengthening Europe as a location for safe, trustworthy and competitive AI. Simplification can be useful – but it should be achieved through clear guidance on the interaction with sectoral legislation, instead of dismantling the horizontal approach.

We therefore call on you, as political decision-makers at both national and European level, to support the preservation of the horizontal approach.

Signatories

TÜV-Verband
AI Policy Lab at Umea University
AlgorithmWatch
ALLAI
DEKRA
ForHumanity
Open Knowledge Foundation
The Future Society
TÜV AI.Lab