

Open Joint Letter on the Digital Omnibus on AI The AI Act must remain a horizontal framework

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Subject: Preserving the scope of the AI Act – the Act must remain a horizontal framework

We, organisations representing civil society, consumers and children's rights, would like to express our serious concerns regarding proposals to change the scope of the AI Act as a part of the AI Omnibus negotiations. The AI Act is the result of careful legislative work and hard-won political compromise, designed to ensure safety, transparency and the protection of consumers' rights in the development and deployment of AI systems. AI Act's harmonised, risk-based horizontal framework ensures that AI systems placed on the EU market are subject to appropriate safeguards regardless of the sector in which they operate.

We strongly urge the Commission and co-legislators to preserve this framework in full. Any change to the scope of Annex I or the classification rules for high-risk AI systems, however limited, risks creating a major loophole, excluding a wide range of industrial and consumer AI systems from its scope and undermining the core safeguards the co-legislators enshrined in the Act. This leaves unaddressed the concerns of a broad coalition of stakeholders, from civil society and doctors to hospitals, children's rights groups and conformity assessment bodies, who have [publicly warned](#) of the consequences of such changes.

The Omnibus must not lead to complexification

The existing sectoral frameworks do not provide safeguards equivalent to those of the AI Act. The instruments listed under Annex I Section A generally do not address AI-specific risks. To the extent that they do, it is only to a very limited extent. The AI Act was designed precisely to fill this gap, regulating risks that sector-specific legislation does not cover. There is no duplication to streamline because there is no equivalence to begin with.

Sectoral legislation cannot substitute the horizontal framework the AI Act provides. Reintroducing AI requirements across approximately twelve separate instruments, each with distinct scopes, definitions and enforcement structures, would demand a legislative undertaking that runs counter to the very objective of simplification. Far from reducing complexity, it would entrench it, creating a fragmented patchwork of sector-specific rules with no common baseline and no consistent level of protection for consumers. This would not simplify the framework. It would dismantle it, shifting responsibility onto sectoral laws ill-equipped to address AI-related risks and producing a governance landscape of greater fragmentation and legal uncertainty for businesses, regulators and consumers alike.

Weakening Annex I would create regulatory gaps with immediate and concerning harms for consumers, including children. In the medical sector, removing AI-embedded devices from the AI Act's scope would leave patients without protection that no sectoral framework is currently equipped to provide. The consequences for children are equally serious: removing toys with AI systems as safety components from the AI Act's high-risk classification would open a structural gap in child protection and directly undermine the recently adopted EU toy safety framework, which relies on the AI Act as its primary tool for managing AI-related risks in toys. Such changes would moreover fail to deliver the simplification promised by the AI Omnibus, trading the existent level of consumer protection for a more fragmented and complex regulatory landscape.

Simplification must not come at the expense of consumer protection

The proposals to amend the scope of the AI Act go well beyond a targeted modification of the AI Act, undermining the existing level of consumer protection in favour of a more fragmented and complex regulatory framework. It reopens settled consumer rights without a clear evidentiary basis or proper impact assessment, contrary to the Commission's Better Regulation principles, which require that any simplification be evidence-based and proportionate. Despite explicit the Commission's assurances that the simplification agenda would not lead to deregulation, the proposed changes to Annex I run directly counter to those commitments. Simplification must serve consumers by reducing unnecessary administrative burden and improving clarity and enforceability of their rights, with no rollback of existing safeguards.

We therefore call on the Commission and co-legislators to defend the integrity and full scope of Annex I in the ongoing trilogue negotiations, and to reject any compromise that would erode the horizontal character of the AI Act and diminish the existing level of consumer protection.

We remain at your disposal and would welcome the opportunity to engage in further dialogue.

Yours sincerely,



Signatories:

- ANEC – The European consumer voice on standardisation
- BEUC – The European Consumer Organisation
- Center for Democracy and Technology (CDT Europe)
- 5Rights Foundation