Simplification Without Deregulation

Why the proposed transfer from Annex I Section A to Section B and broad lex specialis clauses should not be supported — and what to do instead

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The signatories support reducing unnecessary burdens and improving coherence between the AI Act and sectoral legislation. However, some proposed instruments — **transferring legislation from Annex I Section A to Section B** and **establishing a broad lex specialis clauses based on "same objectives"** — would result in deregulation, not simplification and risk producing the opposite of their stated aim. They fragment the horizontal framework, reduce protection, and create the legal uncertainty they claim to resolve.

1. The transfer from Section A to Section B reduces protection

Sections A and B of Annex I are not interchangeable — they reflect **fundamentally different supervisory models**. Section A legislation is generally based on certification and type-approval by conformity assessment bodies against harmonised standards, with full legal responsibility remaining with the economic operator. Section B legislation, such as civil aviation, typically relies on public-authority-led ex ante authorisations prior to market placement. These are structurally distinct governance architectures, and transferring legislation between them cannot be automatic.

More critically, Section B as currently drafted **does not replicate key AI Act obligations**: quality management (art. 17), importer and authorised representative duties (art. 18), EU database registration (art. 49), transparency, incident reporting, and post-market surveillance. Transferring legislation to Section B means these obligations simply *cease to apply*.

The transfer would also undermine the standardisation process. CEN/CENELEC are developing **horizontal harmonised standards** for the AI Act, including prEN 18286 on quality management, already in public enquiry. These standards allow any provider, in any sector, to demonstrate conformity once. The irony should not be lost: *the Omnibus itself was partly justified by the need to delay AI Act obligations precisely because these horizontal standards were not yet ready*. Fragmenting requirements into sectoral frameworks would now require starting separate standardisation processes from scratch — each with its own mandate, timeline, and procedure — reproducing and multiplying the very delays the Omnibus was designed to address.

2. "Same objectives" does not mean same protection

A **broad** lex specialis clause that deems AI Act requirements fulfilled whenever sectoral legislation pursues "the same objectives" conflates **purpose with content**. Sectoral legislation — whether on machinery, financial services (DORA), or medical devices — predates AI as a regulatory category. None was designed to address training data governance, adversarial attacks, algorithmic bias, or AI-specific human oversight. Two regulations may share the broad goal of "ensuring product safety" while differing radically in what they actually require.

Without a clear standard for what counts as "equivalent," this approach creates legal uncertainty, divergent interpretations across Member States, and structural incentives for operators to seek the least demanding conformity pathway — the opposite of a level playing field.

The Annex to this non-paper illustrates this gap by comparing the specific requirements of the AI Act with those of the Machinery Regulation in key areas: training data governance, adversarial attack protection, AI-specific human oversight, and incident governance. In each case, the sectoral legislation pursues broadly compatible objectives but lacks the AI-specific provisions that the AI Act was designed to introduce.

3. Constructive alternatives the signatories can support

The signatories of this document strongly support simplification. And we believe that there are effective ways to achieve so:

- **Targeted amendments to the AI Act:** surgical modifications clarifying how existing sectoral procedures integrate into the AI Act framework and viceversa, identifying potential duplications where they exist, without creating automatic equivalence presumptions.
- **Full "once-only" implementation:** a single application and assessment process under both the AI Act and sectoral legislation, as already introduced by the Omnibus.

- **Bridge standards mandate:** expanding CEN/CENELEC's work to establish how and when AI Act requirements are needed to complement sectoral legislation, with integrated testing procedures.
- **Joint implementation guidelines:** published by the Commission, the AI Office, and sectoral authorities, with unified documentation.

The signatories **can support any evidence-based simplification** that addresses *duly identified duplications*, preserves the AI Act's level of protection, and maintains its horizontal architecture — which is itself a competitive asset for European businesses **as a whole** operating across sectors. They call on the Presidency to uphold the Council's mandate for a targeted, proportionate approach.

Signatories: Denmark, Slovenia and Spain.

Annex 1 – example of how same objectives are not a synomim of equivalence

Regulation (EU) 2023/1230 on Machinery is the sectoral legislation most frequently invoked in the lex specialis debate on quality management. The proposal would imply that Annex IX of the Machinery Regulation is equivalent to Article 17 of the AIA regarding Quality Management System (QMS).

Obligation	***Regulation (UE) 2023/1230 (Machinery)***	***Regulation (UE) 2024/1689 (AI)***
Scope of the QMS	Mandatory for series production (Art. 10.4) and H module (Anexo IX, 2)	Mandatory for providers of high-risk AI systems (Art. 17.1)
Regulatory compliance	Implicit in the series production process (Art. 10.4)	Explicit: must cover a strategy for regulatory compliance (Art. 17.1.a)
Risk Management	Declared as a general principle, not integrated in QMS (Annex III, General Principles)	Integrated in QMS (Art. 17.1.g and Art. 9)
Data Governance	Not specified	Crucial part of the QMS, including a complete data lifecycle definition (Art. 17.1.f)
Post-market monitoring	Register of complaints (Art. 10.4)	QMS is integrated in post-market monitoring system (Art. 17.1.h y Art. 72)
Incident notification	Immediate corrective actions (Art. 10.9)	QMS integrates procedures for reporting of a serious incident (Art. 17.1.i and Art. 73)
Development scope	Refers to manufacturing (Annex IX, 3.2.d)	Refers to development of AI systems, includes quality control and assurance (Art. 17.1. c)
Management responsibility	Organisational structure, responsibilities and powers of the management (Annex IX, 3.2.a)	Explicit mention to accountability framework (Art. 17.1.m)
Proportionality based on company size	Applied to notified bodies (Art. 38.2)	Applied to the implementation of QMS obligations (to provider) (Art. 17.2)