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Q&A: responding to criticisms of the Annex I merger

Background

The proposal to merge Sections A and B of Annex I AI Act has attracted significant opposition from the certification industry, civil society coalitions, trade unions and parts of the Commission. Several of their claims contain factual inaccuracies that have been widely repeated and risk shaping the trilogue debate on false premises. This Q&A responds to those criticisms directly, corrects the record where needed and sets out the evidence-based case for the merger.

The Annex I merger refers to the proposal to delete Section A of Annex I AI Act and incorporate those product categories into Section B. Under the current structure, Section A products – such as machinery, medical devices and radio equipment – must comply with both the AI Act's high-risk obligations *and* their existing sectoral frameworks in parallel. Section B products face AI Act requirements once the relevant sectoral law has been updated to integrate them. The merger would bring all NLF-covered products under the Section B approach, ensuring AI requirements are embedded into sectoral regimes rather than layered on top.

The European Parliament adopted this position on 26 March 2026.[1]

Our key messages are that:

- **We are not asking for deregulation**: we are asking for a single compliance pathway instead of two overlapping ones.
- **The merger does not weaken the AI Act** but makes it work: all high-risk obligations remain, only the procedural channel changes.
- **The Section B model already exists in the AI Act**: the merger extends it consistently to all New Legislative Framework (NLF) products.

[1] https://www.europarl.europa.eu/doceo/document/TA-10-2026-0098_EN.html

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Q&A

1. 'This is a "sector exit," and would exempt sectors like machinery and medical devices from AI Act high-risk rules'

Source of criticism: The 'sector exit' framing has been adopted across a broad coalition. TÜV AI.Lab provided the empirical foundation, finding that 11 out of 12 sectoral laws currently in Section A contain no AI-specific requirements and arguing that moving these products to Section B therefore amounts to a *de facto* exemption. The TIC Council has amplified this argument, warning that the merger would fragment AI-specific assessment competencies and create a regulatory vacuum lasting 5–10 years. The German Trade Union Confederation (DGB) wrote to the Federal Minister of Labour on 23 March 2026 warning that the merger would strip AI Act protections from workers in human-machine collaboration environments. A civil society open letter dated 7 April 2026 – signed by 32 organisations including BEUC, EDRi, CDT Europe, CPME and HOPE – endorsed the same position, arguing that the merger creates a 'structural gap' in consumer, patient and fundamental rights protection. Parts of the Commission and the AI Office have also signalled sympathy with this characterisation.

Our response

This criticism rests on a fundamental misreading of the proposal. The merger does not remove or undermine the AI Act's requirements: it changes *how* they are applied and *through which channel*.

TÜV AI.Lab's finding that 11 out of 12 sectoral laws contain no AI-specific requirements describes the *status quo*, not the merger's outcome. Under the Section B approach, AI requirements are integrated into the relevant sectoral legislation. The AI Act's high-risk classification and essential requirements remain in force but are delivered through the sectoral framework that already governs the product, rather than imposed in parallel.

What the merger does is ensure that products embedding AI already subject to stringent, sector-specific EU safety law – laws that were specifically designed to protect users and workers – are assessed under those frameworks rather than through a duplicative parallel process. The merger allows AI-specific requirements to be integrated into that framework through secondary legislation, rather than running a separate AI Act conformity assessment on the same product.

2. 'The merger fragments the AI Act's horizontal approach.'

Source of criticism: The Commission has argued the AI Act was deliberately designed as a horizontal, cross-sector framework, and that pushing AI requirements into sectoral regimes would weaken this architecture, producing inconsistent standards and undermining the AI Office's cross-sector oversight role.

The testing, inspection and certification industry – TIC Council, TÜV AI.Lab and others – argues the merger would fragment AI-specific assessment competencies, create a regulatory vacuum of 5–10 years and amount to *de facto* deregulation. A broader civil society coalition (open letter of 7 April 2026) has endorsed these concerns.

Our response

The current dual-track system is itself a source of fragmentation and unpredictability. Under the current structure, a manufacturer of an industrial robot or an AI-enabled medical device must run two separate conformity assessment procedures on the same product: one under the AI Act, with its own requirements for technical documentation, risk and quality management systems, human oversight architecture and bias testing; and one under the applicable sectoral legislation, such as the Machinery Regulation or the Medical Devices Regulation (MDR). These procedures overlap in substance, but are legally distinct and cannot be merged into one.

This forces manufacturers to identify notified bodies designated under both regimes, a requirement that is already creating bottlenecks. The designation process remains unclear and may repeat the delays already experienced during MDR implementation. A manufacturer that cannot find a dually designated notified body must engage two separate notified bodies for the same product or cannot legally place its product on the EU market at all.

The merger creates a single compliance pathway, making the horizontal approach work at sectoral level.

The AI Act already contains this two-track logic in its own text. Section B was created for exactly this purpose, and already contains an NLF directive.[2] Extending it to all NLF products in current Section A is not a deviation from the AI Act's architecture. No one argues that AI in cars or aircraft, sectors already in Section B, is regulated inconsistently with the rest of the AI Act, or that the horizontal approach has been abandoned for those products. If the Section B model maintains horizontality for vehicles, there is no principled reason it cannot do so for medical devices and machinery.

To preserve the AI Act's horizontal approach and make sure that the Section A legislation would not diverge from the AI Act when merged into section B, the European Parliament proposed specifying that the sectoral implementation work carried by the Commission 'shall not go beyond the requirements laid down in [the AI Act].'[3]

The concern that sectoral market surveillance authorities will interpret AI requirements inconsistently is already present under the current structure. Today, AI Act market surveillance is allocated among a large number of national authorities, not managed centrally by the AI Office. The AI Office's cross-sector role is primarily for general-purpose AI models, not for Annex I product conformity.

3. 'The merger will delay the application of AI requirements to regulated products'

Source of criticism: Multiple voices – including TÜV AI.Lab, parts of the Commission and the civil society coalition – argue that the merger would require amending twelve sectoral laws and create a regulatory vacuum lasting years whilst delegated acts and sectoral standards are developed, and that it is better to apply the AI Act's horizontal requirements directly under Section A.

[2] Marine equipment (Directive 2014/90/EU).

[3] See the Parliament's amendments 25 and 75.

Our response

The question is not whether the merger pathway takes time, but whether the *status quo* is better. It isn't.

AI Act requirements do not currently apply smoothly to Section A products. Harmonised standards for most Section A product categories do not yet exist. Notified body capacity is demonstrably insufficient to handle the conformity assessment workload. The Commission's own omnibus proposal already includes extended transitional periods for Section A products in recognition of this. 'Apply the AI Act now via Section A' is not a viable alternative: delay is already baked into the status quo.

The delay of the high-risk obligations, which would anyway apply to the whole of Annex I, creates the window needed for the necessary adaptation of sectoral frameworks under the Section B model. Any additional time required beyond what the omnibus delays already provide would in practice be negligible.

Under the current trajectory, regulated product manufacturers under Section A face even worse uncertainty. The horizontal AI standards being developed by CEN-CENELEC JTC 21 will only partially cover the AI Act's legal requirements even when adopted, and may not work for all sectors. The Commission has signalled that many of these horizontal standards will not be able to give presumption of conformity, and CEN-CENELEC's own internal assessment acknowledges that the 'time-boxed' delivery approach means significant gaps in legal coverage.[4]

Without presumption of conformity through harmonised standards, manufacturers under Section A cannot self-assess. They are forced into mandatory third-party conformity assessment by AI Act-designated notified bodies. These notified bodies, for the most part, do not yet exist in sufficient numbers: only around 20 of 44 medical device notified bodies intend to seek designation under the AI Act.[5] This is the scenario the certification industry is defending, as the absence of a merger guarantees a stream of mandatory third-party assessments. A system that generates more work for the certification industry is not inherently safer; it is just more costly.

In the merger scenario, the pathway to usable standards is materially better. Once the Commission adopts delegated acts integrating AI Act requirements into sectoral law, it can issue standardisation mandates to CEN-CENELEC, where sector-specific technical committees can adapt horizontal AI standards to their product context. Provided the Commission facilitates presumption of conformity through these vertical standards, manufacturers would have far greater clarity on the standards they must apply and could rely on self-assessment under existing NLF conformity assessment modules. The cost of compliance would drop dramatically.

TÜV AI.Lab's timeline also appears to assume that the Section B route requires entirely new sectoral AI legislation through ordinary legislative procedure. That is not how the delegated act mechanism works. The

[4] See 'EU's AI standard setters face hard balancing act with disappointment in sight,' *MLex*, 14 November 2025, available at https://www.mlex.com/mlex/articles/2411168/eu-s-ai-standard-setters-face-hard-balancing-act-with-disappointment-in-sight.

[5] Whilst many AI-enabled medical devices will fall under both the medical device regulations and the AI Act, not all notified bodies designated under the former intend to seek designation under the latter. According to TEAM-NB, only about 20 out of 44 notified bodies plan to apply. The designation process itself remains unclear and may repeat earlier delays experienced for medical devices. See Politico, 'Medtech's AI deep dive,' available at https://pro.politico.eu/news/medtechs-ai-deep-dive.

Parliament's proposal empowers the Commission to integrate AI Act requirements through secondary legislation, a materially faster route.

4. 'Consumers/patients would be put at even greater risk if toys, smartwatches and medical devices are excluded from the AI Act'

Source of criticism: BEUC (The European Consumer Organisation); CPME (Standing Committee of European Doctors) and HOPE (European Hospital and Healthcare Federation)

Our response

No product is excluded. The merger does not remove any product from the AI Act's scope. The classification of AI systems in these products as high-risk is unchanged. The obligations that apply – transparency, data governance, accuracy, robustness, human oversight – remain in full.

What changes is the procedural channel through which those obligations are assessed and enforced. Medical devices are amongst the most heavily regulated products in the EU market, subject to clinical evaluation reports, notified body scrutiny and post-market surveillance under the MDR. Medical devices manufacturers already must put in place risk management and quality management systems within their sectoral framework. Adding a separate AI Act conformity process on top of this, with overlapping elements, does not increase consumer protection, but adds administrative cost and legal uncertainty without generating any additional safety benefit.

5. 'The AI Act should not be dismantled before it has even been applied'

Our response

This argument mistakes a structural reform for an abandonment. The AI Act is not being dismantled: it entered into force in August 2024 and its core framework remains fully intact. Key provisions regarding the prohibitions of the most harmful practices and rules for the most powerful general-purpose AI models have been applicable since February and August 2025. What is being reformed is one specific interaction mechanism between the AI Act and pre-existing sectoral laws, for a defined category of products.

The Commission itself acknowledged, in the AI omnibus proposal, that the current implementation architecture has structural flaws, specifically, the complexity and delays in drafting harmonised standards and the insufficient capacity of notified bodies, many of which may not be recertified under the AI Act. The omnibus was introduced precisely because the *status quo* cannot deliver the AI Act's objectives.

Delaying the AI Act's high-risk obligations without fixing the underlying architectural flaw – the Annex I problem – means that in 2027 or 2028, manufacturers will face the same compliance situation, merely deferred. The merger addresses the root cause.

6. 'Section B was not designed to cover NLF-type legislation, unlike Section A. Moving NLF products there creates a legal vacuum and will undermine the NLF approach'

Our response

First, Section B already contains an NLF directive.[6] Second, this criticism overstates the gap between current Section B legislation and NLF law. The three main sectoral regimes currently in Section B (motor vehicles, aviation and marine equipment) are not NLF, but they are not structurally alien to it either. They share the features that matter: they impose mandatory pre-market conformity assessments; they rely on type-approval or certification by designated independent bodies; they use delegated and implementing acts to update technical requirements; and they depend on harmonised or equivalent standards to define compliance criteria. The NLF does the same through a different architectural label. The operational tools are closely analogous.

More fundamentally, the Section B logic was designed to solve a specific problem: a product that is already subject to a rigorous, sector-specific conformity regime should not be required to run a separate, parallel AI Act conformity process on top. That problem is entirely independent of whether the sectoral law follows NLF conventions or not. It applies with equal force – arguably greater force – to NLF products, because NLF conformity assessments are highly standardised, module-based and already involve notified bodies performing precisely the kind of technical scrutiny the AI Act is designed to achieve. The duplication is more acute, not less, for NLF products.

7. 'The AI Act already ensures appropriate interaction between the AI Act and sectoral legislation: the existing provisions make the merger unnecessary'

Source of criticism: The AI Office has argued that existing provisions in the AI Act, in particular Art. 8, already ensure appropriate interaction between the AI Act and sectoral legislation, and that the horizontal approach provides greater consistency than a fully sectoral one.

Our response

Arts 8(2) and 43(3) AI Act are an attempt to mitigate the problem of duplication and additional burden. Art. 43(3) provides that for Section A Annex I products, the provider follows the sectoral conformity assessment procedure, and that the AI Act's substantive requirements shall be part of that assessment, with the sectoral notified body entitled to cover both. Art. 8(2) adds that providers may integrate their AI Act testing, reporting and documentation into the existing sectoral documentation and procedures.

But neither provision resolves the operational burden. Three concrete problems remain fully intact.

First, the absence of any mechanism to rationalise overlaps. Under Art. 43(3), the AI Act's requirements are incorporated into the sectoral assessment in full, with no mechanism to account for the substantial areas where they duplicate obligations that already exist under sectoral law, or where definitions or other elements are misaligned.[7] The MDR already requires extensive risk management systems, clinical evaluation, quality

[6] Marine equipment (Directive 2014/90/EU).

[7] For instance, the definition of 'safety component' in the Machinery Regulation does not exactly cover the same elements as the AI Act, whilst the notions of 'risk' and 'risk assessment' are understood differently under the MDR compared to the AI Act. Key concepts such as 'substantial modification'

management frameworks and post-market surveillance. The Machinery Regulation already addresses safety architecture in automated environments, as well as risk assessment and reliability/robustness. Where the AI Act's requirements and sectoral requirements cover the same ground, Art. 43(3) simply runs both: the integrated procedure reduces administrative steps but cannot eliminate substantive duplication. The Annex I merger solves this at the root: by embedding AI requirements into sectoral frameworks through secondary legislation, it creates the legal space to align and rationalise overlapping obligations and definitions, delivering the same level of protection through a coherent single framework rather than two overlapping ones.

Second, the notified body bottleneck. Under Art. 43(3), a sectoral notified body can only cover the AI Act requirements if its compliance with the AI Act's specific notified body requirements has been separately assessed. Most sectoral notified bodies have not completed this step. According to TEAM-NB, the European Association for Medical Devices of Notified Bodies, only around 20 of 44 medical device notified bodies intend to seek designation under the AI Act.[8] Until that process is completed, manufacturers cannot access the integrated procedure Art. 43(3) provides for in theory. The bottleneck is real and immediate, an assessment also shared by TEAM-NB.[9]

Third, the harmonised standards gap. Where sectoral legislation permits self-certification – allowing a manufacturer to apply all relevant harmonised standards internally instead of using a third-party assessment – Art. 43(3) conditions this option on AI Act-specific harmonised standards also existing and being applied. For most Section A product categories, those standards are unlikely to offer presumption of conformity.[10] Manufacturers who would ordinarily qualify for self-certification under their sectoral framework are therefore effectively pushed into mandatory third-party assessment, at significant additional cost.

Taken together, Arts 8(2) and 43(3) do not offer substantive relief from the compliance burden that the dual-track structure generates. The Annex I merger delivers what these provisions gesture towards but cannot achieve: a genuinely integrated compliance pathway in which AI requirements are embedded into sectoral frameworks, with no residual AI Act layer running alongside.

8. 'The AI Act provides legal certainty for medical device manufacturers; the merger would undermine that.'

Source of criticism: CPME and HOPE have argued in an open letter that the AI Act brings clarity and consistency for manufacturers and deployers of AI systems in healthcare, and that moving medical devices out of Section A would weaken that framework.

(Machinery) or 'significant/substantial change' (MDR) collide with the AI Act's similar-yet-different interpretation of such modification assessment.

[8] Whilst many AI-enabled medical devices will fall under both the medical device regulations and the AI Act, not all notified bodies designated under the former intend to seek designation under the latter. According to TEAM-NB, only about 20 out of 44 notified bodies plan to apply. The designation process itself remains unclear and may repeat earlier delays experienced for medical devices. See Politico, 'Medtech's AI deep dive,' available at https://pro.politico.eu/news/medtechs-ai-deep-dive.

[9] TEAM-NB states that '[d]elays are likely to cause a shortage of designated NBs,' and that '[d]epending on the practical interpretation of the overall scope of the AI Act [there is an] inherent risk of a major disruption of the medical device software (MDSW) market.' See https://www.team-nb.org/wp-content/uploads/2025/04/Team-NB-PositionPaper-EU-AI-Act-V2-20250409.pdf.

[10] See question 3 in this document for more detail.

Our response

The Commission itself proposed moving MDR/IVDR from Section A to Section B of the AI Act in its targeted simplification proposal of December 2025. The Commission's own assessment confirms what manufacturers have been saying: the dual-track structure does not deliver legal certainty for medical devices, but compounds uncertainty.

The AI Act's horizontal framework sits uncomfortably with the existing definitions and concepts in MDR/IVDR. Two examples illustrate the structural problem:

- 'Substantial modification' vs. 'significant change.' The AI Act introduces the concept of 'substantial modification,' defined as a change to an AI system after its placing on the market or putting into service that was not foreseen in the initial conformity assessment. This concept is not aligned with the MDR/IVDR framework, which uses 'significant change' (and, in some contexts, 'substantial change') as the trigger for regulatory action. A manufacturer running a dual-track assessment must determine which concept applies to the same product update, and the two frameworks may give different answers.
- The definition of 'risk.' The AI Act requires risks to be reduced 'as far as technically feasible.' The MDR and IVDR rely on a benefit–risk balance, essential to healthcare delivery, that accepts justified risks in light of clinical benefit. These are fundamentally different regulatory philosophies applied to the same product. A manufacturer cannot simultaneously minimise all risk (AI Act) and accept justified risk where clinical benefit warrants it (MDR/IVDR).

These definitional conflicts mean that horizontal AI harmonised standards, even once delivered, will be of limited utility as a compliance tool for the medical technology sector, because the standards are built on AI Act concepts that do not map onto MDR/IVDR terminology. Sector-specific standards developed through the merger's delegated act pathway can resolve these misalignments.

When the EU transitioned from the Medical Device Directives to the MDR/IVDR, certification times doubled from 9–12 months to 12–24 months, and costs rose by 260%. A poorly implemented AI Act overlay, layering horizontal AI requirements on top of an already complex sectoral regime, would compound these delays further.

'This is industry lobbying dressed up as simplification – a vehicle for deregulation'

Source of criticism: The DGB and others have argued that the Annex I campaign is a pretext to weaken AI safety obligations for European manufacturers.

Our response

This characterisation is factually inaccurate and obscures the substantive debate. The 48 associations that co-signed the March joint industry AI omnibus letter span automotive, agriculture, medical devices, machinery, electronics and beyond.[11] The campaign was built on concrete, verifiable case studies provided by manufacturers showing where dual compliance creates real operational problems.

[11] https://cdn.digitaleurope.org/uploads/2026/03/Omnibus-joint-industry-letter.pdf.

The ask is procedural, not substantive. We are not asking to remove any safety requirement. We are not asking to eliminate any conformity assessment. We are not asking to reduce the AI Act's scope. We are asking for a single compliance pathway that delivers the same level of protection without requiring manufacturers to run two separate certification processes on the same product.

The €31 billion cost estimate over five years – covering 2.2 million European manufacturers – reflects the administrative and compliance burden of the dual-track system. A 50-employee SME integrating an AI safety component faces initial compliance costs approaching €600,000 and recurring annual costs of €150,000 under the current framework. These numbers are based on Commission methodology.[12] Calling industry's response to these figures 'deregulation lobbying' dismisses the legitimate operational reality of the companies that will have to implement this legislation.

10. 'Most Member States are neutral or opposed – the Annex I merger lacks political support in the Council'

Our response

Several Member States are in an active internal review phase, including France and Czech Republic. Economy ministries in France, Italy, Spain, Sweden, Finland and Poland have shown openness to the merger or to related simplification approaches. Germany's *lex specialis* proposals, which would give sectoral rules precedence over the AI Act where they overlap, reflects the same underlying concern about duplicative obligations, even if it takes a different legislative form.

The Parliament's position supporting the Annex I merger is strong and cross-party, creating a clear mandate for trilogues.

[12] Notably from the study supporting the AI Act's impact assessment.

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