

16 FEBRUARY 2026

# AI omnibus: a necessary pause to enable real simplification

## Executive summary

Europe's ambition to lead in AI will only succeed if the AI Act can be implemented in a way that is credible, predictable and workable across sectors. The AI omnibus is therefore a pivotal moment not just to adjust timelines, but to determine whether simplification will be real.<sup>1</sup>

At present, the proposal and surrounding debate miss the core issue. The need for a delay of the high-risk AI requirements is widely acknowledged: harmonised standards will not be ready, guidance remains pending and enforcement authorities are still being set up in several Member States. Without this infrastructure, compliance is not realistically possible.

But by bundling a necessary postponement with a modest set of substantive amendments, the AI omnibus proposal creates a strong political incentive for Council and Parliament to move quickly because the delay must enter into force in time. Delaying implementation and reforming substance require different timelines, different scrutiny and different political trade-offs. Treating them as one forces co-legislators to choose urgency over quality – and will lock in avoidable design flaws for years to come. That would be a huge missed opportunity.

That is why DIGITALEUROPE urges co-legislators to **formally request a separate proposal postponing the entry into application of the high-risk AI requirements**, to be adopted under accelerated procedures. This would provide immediate legal certainty for companies and authorities, avoid a compliance cliff driven by missing standards and guidance, and remove the artificial time pressure currently distorting the legislative debate.

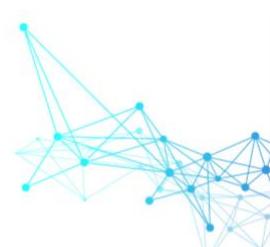
Once the timeline risk is addressed, Council and Parliament can do what the omnibus was meant to enable in the first place: properly assess whether the AI Act works in practice, and where it needs to be improved.

Since early 2025, DIGITALEUROPE has been leading industry calls for AI Act simplification, which culminated with the publication of detailed recommendations in June 2025.<sup>2</sup> This paper builds on these simplification recommendations, which reflect broad industry consensus, and responds to the Commission's proposal by restating the key changes needed:

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<sup>1</sup> COM(2025) 836 final.

<sup>2</sup> See DIGITALEUROPE, *Digital simplification package: Our AI recommendations*, available at <https://cdn.digitaleurope.org/uploads/2025/06/Digital-simplification-package-AI.pdf>.



- » **Sectoral integration:** The Commission's own proposal to move medical devices to Annex I, Section B confirms what industry has long argued – AI requirements must be implemented through sectoral frameworks for regulated products.<sup>3</sup> This logic should be extended to other comparable regimes, such as machinery and radio equipment.
- » **Legacy clause for existing systems:** The legacy clause must be embedded in operative provisions, not left in recitals, to reflect how AI systems are developed, deployed and updated.
- » **Coherent data governance:** AI-related processing of personal data should be governed through a single, GDPR-based framework, rather than parallel and prescriptive regimes that undermine accountability and flexibility.
- » **Proportionate obligations:** Registration requirements, duplicative impact assessments, source code access provisions and CE marking for software should be removed where they add burden without improving safety.

None of these issues can be resolved properly under the current 'adopt now or lose the delay' dynamic. Separating the timeline adjustment from the substantive debate is therefore the condition for delivering an AI framework that is enforceable, investment friendly and fit for Europe's industrial reality, prioritising implementation over new legislative initiatives or additional regulatory provisions.

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<sup>3</sup> In December 2025, the Commission's health package (COM(2025) 1023 final) proposed moving medical devices and in vitro diagnostic medical devices from Section A to Section B of Annex I AI Act. This change reflects sustained industry advocacy, and demonstrates at political level that sectoral integration of AI requirements is both feasible and preferable. This approach provides a clear precedent for extending the same approach to other regulated products facing similar implementation constraints.

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## Separating the clock from the content

AI will be central to Europe's technological competitiveness across manufacturing, healthcare, energy, finance, mobility and more. For this reason, the AI omnibus should be a critical moment to ensure that the AI Act can both be implemented effectively and work well in practice over time.

At this stage, two issues have become apparent. They require different responses and should not be treated as one:

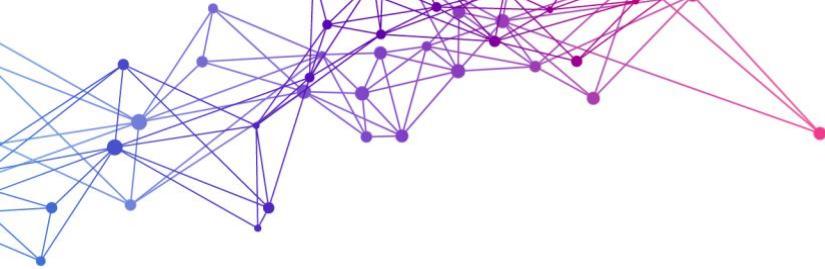
- ▶ First, **the AI Act is not yet ready to be implemented**. Harmonised standards will not be ready in time;<sup>4</sup> several Member States are still in the process of designating and operationalising competent authorities; core guidance documents are pending.<sup>5</sup> Without this machinery, companies and public authorities cannot realistically comply. This justifies **postponing the entry into application** of the high-risk AI requirements so that compliance can be based on clear standards, functioning authorities and consistent enforcement.
- ▶ Second, **parts of the AI Act require substantive reconsideration**. It is increasingly clear that certain provisions – particularly those affecting regulated industrial products and complex value chains – will be difficult to apply as currently designed. Properly addressing issues of sectoral alignment, conformity assessment, proportionality and interaction with existing safety legislation requires time and genuine political discussion.

The current AI omnibus proposal, however, is handling these two issues together. By bundling a necessary delay with a limited set of substantive amendments, the proposal creates a strong incentive for Council and Parliament to prioritise speed over simplification. To ensure that the delay takes effect in time, co-legislators are being pushed to adopt the entire package quickly, leaving no room to assess whether well-founded

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<sup>4</sup> Harmonised standards are the primary tool enabling practical compliance with the AI Act, as they translate legal requirements into concrete technical and organisational measures and provide a presumption of conformity. Whilst voluntary, they are the preferred compliance route for most companies, particularly SMEs and startups with limited regulatory resources. Standardisation work could only begin in earnest after adoption of the AI Act, and has been slowed by the novelty and complexity of the framework. Current estimates indicate that only a limited number of European standards will be available by mid-2026, with several not ready until late 2026 or 2027, whilst supporting international standards are expected between April and September 2026. See Report from WG 1 'Strategic Advisory Group (SAG)' to the CEN-CENELEC Joint Technical Committee 21 (JTC 21) meeting of November 2025. Even once published, organisations typically require additional time to integrate standards into development, governance and compliance processes, alongside emerging codes of practice and guidance.

<sup>5</sup> The AI Act has already begun to apply, with prohibitions on harmful AI practices in force since February 2025 and transparency, safety and security obligations for certain general-purpose AI models applicable since August 2025, supported by a code of practice in the absence of harmonised standards. Member States were required to designate national enforcement authorities by August 2025, but this has only been completed in a limited number of cases, reflecting the complexity of coordinating across sectors and regulators. The next major milestone is 2 August 2026, when high-risk AI requirements under Annex III and additional transparency obligations are scheduled to apply; several authorities have indicated that, even once designated, full enforcement capacity is unlikely before 2027, in particular due to the lack of supporting standards and guidance being repeatedly delayed.



improvements should be considered.<sup>6</sup> The result would be a rapid political agreement that delivers a delay, but locks in a sub-optimal reform of the AI Act.

This outcome is avoidable. The solution is to separate the timeline adjustment from the rest of the AI omnibus. **A targeted proposal postponing the entry into application of the high-risk AI requirements should be adopted quickly, using an accelerated procedure.** This separate delay proposal, clearly recognising December 2027 and August 2028 as default application deadlines, would provide immediate legal certainty for companies and authorities, without prejudging the outcome of discussions on substantive changes.<sup>7</sup>

Once the timing pressure is removed, Council and Parliament would be able to properly assess the merits of the Commission's proposed amendments, as well as alternative or complementary proposals from stakeholders. This is the only way to ensure that simplification is real, proportionate and durable rather than a fictional by-product of urgency.

### Transparency grace period for AI deployers

The same logic that justifies postponing high-risk AI requirements also applies to transparency obligations: where implementation tools and guidance are not yet available, enforcement deadlines must be adjusted.

The AI omnibus proposes a six-month enforcement delay for certain transparency obligations applying to legacy generative AI systems, corresponding to the requirement for providers under Art. 50(2) to mark AI-generated content.<sup>8</sup> However, no corresponding grace period is granted to AI deployers, even though deployer obligations depend on the availability of AI-marking solutions and on guidance and a code of practice that are not expected before mid-2026.<sup>9</sup> Both deployers and providers risk being required to comply with obligations that cannot yet be implemented in practice.

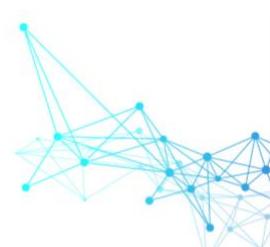
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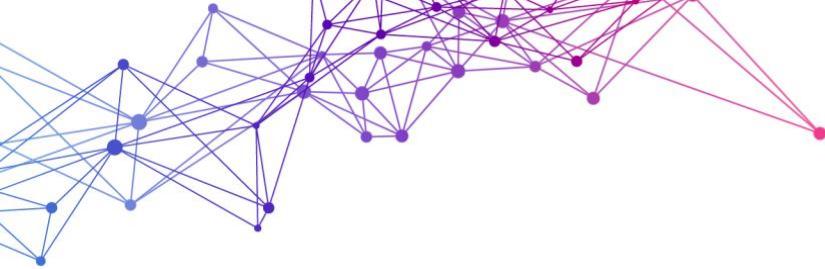
<sup>6</sup> Under the EU's ordinary legislative procedure, negotiations take time: during the 2019–2024 Parliament mandate, the average duration was around 20 months, while the AI Act itself took 39 months from proposal (April 2021) to publication (July 2024). This is considerably longer than the few months currently envisaged by co-legislators for the adoption of the AI omnibus, making it unrealistic to assume that substantive amendments can be meaningfully assessed, debated and agreed within the available timeframe.

<sup>7</sup> The AI omnibus proposes a two-tier delay of high-risk AI obligations: by default, Annex III systems would apply from December 2027 and Annex I systems from August 2028, but the Commission could trigger earlier application within six months if it considers that 'adequate measures in support of compliance' are available. Whilst linking compliance timelines to standards availability is conceptually sound, this mechanism leaves key dates contingent on a Commission assessment. Industry typically needs at least 12 months after standards are formally cited to integrate them into products, processes and governance. A separate delay proposal should clearly recognise December 2027 and August 2028 as the default application deadlines.

<sup>8</sup> New Art. 111(4).

<sup>9</sup> No harmonised standards are foreseen for the transparency obligations set out in Art. 50 AI Act. The Commission launched work in autumn 2025 on guidance and a code of practice for AI-generated content, which are not expected before June 2026 at the earliest, shortly before the rules enter into application. Several Art. 50 obligations, including provider and deployer information duties towards natural persons, will be addressed only through guidance rather than the code of practice, with publication also expected close to summer 2026.





For this reason, the **grace period should also cover obligations under Arts 50(1)–(4) and be extended to 12 months**, allowing both providers and deployers sufficient time to implement the forthcoming guidance and code of practice.

## Fixing the content

Several elements of the AI omnibus proposal move in the right direction, particularly those aimed at administrative simplification. These include the removal of the obligation to register certain non-high-risk AI systems under Art. 6(3) in a separate database; the replacement of the mandatory post-market monitoring template with non-binding guidance; and measures to support innovation, such as the introduction of a legal basis for real-world testing under Annex I, Section B through a new Art. 60a, as well as the possibility of establishing an EU-level regulatory sandbox.

Nevertheless, many key issues remain unresolved. These will need to be addressed during the interinstitutional negotiations to ensure that the omnibus delivers true simplification.

## Integrate AI requirements into sectoral laws

The AI Act was designed as a horizontal framework. Its implementation, however, is already exposing structural limits when applied directly to products governed by long-standing sectoral safety regimes. This is particularly evident for Annex I products, where AI requirements are layered on top of existing conformity frameworks without a clear integration pathway.

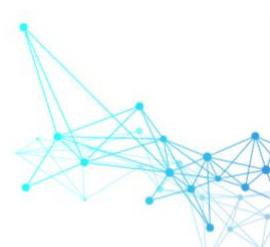
Drafting of AI harmonised standards has proven slower and more complex than anticipated, whilst manufacturers and notified bodies remain uncertain about how AI standards will align with existing product-specific standards. In parallel, conformity assessment bodies designated under sectoral legislation are not automatically equipped – or willing – to take on parallel designation under the AI Act, creating bottlenecks in already capacity-constrained systems. These frictions are structural.

The **Commission's own recent proposal to move medical devices and in vitro diagnostic medical devices from Annex I, Section A to Section B** is therefore a critical turning point.<sup>10</sup> It constitutes an explicit recognition that direct application of the AI Act to heavily regulated products does not work in practice, and that AI requirements must instead be implemented through sectoral legislation. This approach preserves safety, avoids duplication and maintains the integrity of existing conformity assessment systems.

That logic does not stop with medical devices. **Other Annex I product regimes – most notably machinery, but also radio equipment and other regulated products – operate under comparable governance conditions:** established safety legislation, mature standards ecosystems, reliance on notified bodies and limited assessment capacity. They face the same risks of misalignment, duplication and market disruption if AI requirements are applied in parallel rather than integrated.

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<sup>10</sup> On 16 December 2025, the Commission presented a health package proposing revisions to the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). The package includes an amendment to the AI Act moving MDR and IVDR from Annex I, Section A to Section B, recognising that interplay challenges are best addressed by integrating AI Act requirements into sectoral frameworks. This approach should be adopted consistently, including by reflecting the Section B move directly in the AI omnibus to provide early legal certainty to the medical devices sector. See Recital 23 and Art. 4, COM(2025) 1023 final.



The measures proposed in the AI omnibus to streamline notified body designation are welcome but do not resolve the absence of a coherent integration model.<sup>11</sup>

For these reasons, **Annex I should be streamlined by extending the Section B integration model to all Annex I products**, allowing AI requirements to be implemented through sectoral frameworks rather than alongside them. This would enable AI obligations to be translated into sector-specific contexts, preserve existing conformity pathways, and ensure that harmonised AI standards are applied in a manner consistent with sectoral risk management and supervision.

To ensure legal certainty, the AI omnibus should also clearly state that, whilst sectoral regulatory regimes referred to in Annex I legislation serve as the primary implementation frameworks for AI requirements, **the AI Act must remain a maximum-harmonisation instrument** – ensuring that sector-specific measures (secondary legislation or technical specifications) do not add to, or expand beyond, AI Act requirements. This would avoid regulatory gold-plating and preserve a consistent understanding of ‘state of the art’ across sectors. Where sectoral supervisors already have the necessary tools and access, they should act as lead authorities for AI-related oversight.

## Add a robust legacy clause

The legacy clause set out in Art. 111(2) is a crucial safeguard for legal certainty and continuity. It determines whether AI systems placed on the market before the application of new high-risk requirements can continue to be used without retroactive compliance.

Recital 21 of the omnibus provides essential details regarding how this clause will apply in practice. It clarifies that **once placement on the market (or into service) has occurred for an individual AI system unit before the entry into application of high-risk requirements, other AI system units of the same type and model also benefit from the legacy clause**, even if placed on the market after entry into application. If substantial modifications are carried out on the AI system, all future units, as well as those in operation, would have to be made compliant.<sup>12</sup>

This clarification is essential as it recognises that the notion of ‘individual product unit’ is not well suited to AI systems, i.e. standalone or embedded software distributed through complex supply and update channels. Additionally, certain categories of products with long development, certification and production cycles need to have market placement considered at product-model or -type level, rather than for each individual unit.<sup>13</sup>

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<sup>11</sup> The AI omnibus proposes a streamlined procedure for new notified bodies and for those already active in the sectors listed in Annex I, Section A, based on a single application and assessment process (new Art. 28(8)).

<sup>12</sup> The concept of ‘substantial modification’ needs to be clarified so as not to capture limited changes and updates to AI systems. Similar considerations apply to other new placement-on-the-market legislation such as the Cyber Resilience Act (Regulation (EU) 2024/2847). For an elaboration, see the ‘Substantial modification’ section in DIGITALEUROPE, *Developing guidelines for the Cyber Resilience Act*, pp. 12–15, available at [https://cdn.digitaleurope.org/uploads/2024/09/Developing-guidelines-for-the-Cyber-Resilience-Act\\_DE.pdf](https://cdn.digitaleurope.org/uploads/2024/09/Developing-guidelines-for-the-Cyber-Resilience-Act_DE.pdf).

<sup>13</sup> For instance, products under the vehicle type-approval, machinery or medical devices frameworks.

However, the fact that these clarifications are set out only in a recital of the omnibus proposal, rather than in the operative provisions of the AI Act itself, does not provide sufficient legal certainty for authorities or market actors. **These clarifications should be integrated into Art. 111 AI Act.**<sup>14</sup>

## Align legal bases with the GDPR

**The AI and digital omnibus proposals risk entrenching a fragmented approach to AI-related data processing by maintaining parallel regimes across the AI Act and the GDPR.** For the purposes of public interest, the AI omnibus proposes a new Art. 4a in the AI Act, largely relocating existing Art. 10(5) to regulate the processing of special categories of personal data for bias detection and correction through a prescriptive, self-contained set of conditions. In parallel, the digital omnibus proposes targeted amendments to the GDPR – notably a new Art. 9(2)(k) and Art. 88c – to clarify how personal data, including special categories, may be processed in the development and operation of AI systems under the GDPR's risk-based framework.<sup>15</sup>

Proposed Art. 4a relocates Art. 10(5) into a standalone provision and carries over its core flaw: an exhaustive checklist of safeguards that must be met in all cases, irrespective of context. Whilst these safeguards may be appropriate in certain situations, embedding them rigidly in the AI Act undermines the GDPR's accountability-based model, removes the flexibility needed for effective bias detection and mitigation, and can also put companies in conflict with other legal obligations.<sup>16</sup>

The GDPR amendments proposed in the digital omnibus provide a more appropriate foundation. Proposed Art. 9(2)(k) clarifies the lawful processing of special categories of personal data in the context of AI – which could explicitly include bias detection and correction – and proposed Art. 88c clarifies that the development, testing and operation of AI systems may rely on legitimate interest, subject to safeguards. Even though these provisions themselves require refinement – to ensure they are not neutralised by accompanying obligations – they are structurally better suited to govern AI-related data processing.<sup>17</sup>

For this reason, the co-legislators should avoid maintaining two parallel regimes. We see two coherent options:

- Either regulate AI-related personal data processing exclusively through the GDPR, by refining and finalising the digital omnibus provisions, and delete Art. 4a and Art. 10(5) from the AI Act; or

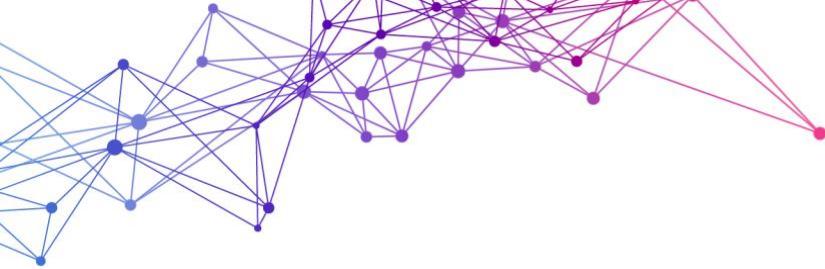
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<sup>14</sup> There will also be a need to address potential frictions with New Legislative Framework (NLF) product legislation listed in Annex I, which is based on the Blue Guide's (2022/C 247/01) unit-by-unit 'placement on the market' logic. Alignment is needed to ensure that legacy clause protection and substantial-modification triggers can be applied at system or model level for AI, without creating conflicting compliance obligations under sectoral product rules.

<sup>15</sup> Arts 3(3) and (15), COM(2025) 837 final.

<sup>16</sup> In particular, mandatory requirements to delete special categories (Art. 4a(e), mirroring current Art. 10(5)(e)) once bias is 'corrected' may prevent companies from complying with data retention, audit, traceability or regulatory reporting obligations under sectoral legislation. It also limits the ability to demonstrate ongoing compliance over time.

<sup>17</sup> For more on our suggested refinements, see pp. 8–9 of DIGITALEUROPE's position on the digital omnibus proposal, available at <https://cdn.digitaleurope.org/uploads/2026/02/Digital-omnibus-a-first-step-and-what-must-come-next-now.pdf>.



- Regulate it exclusively through the AI omnibus, but by transplanting the corrected GDPR-based language and logic into the AI Act, rather than preserving the current prescriptive approach.

## AI literacy: preserve intent, avoid new layers

DIGITALEUROPE has consistently supported the underlying objective of strengthening AI skills and awareness contained in the AI Act's Art. 4, including by providing appropriate AI training and education to employees, customers and others who develop, operate or use AI systems.<sup>18</sup>

Art. 4 establishes an obligation of means, requiring organisations to take reasonable steps to promote AI literacy, without imposing measurable outcomes or results. Many companies have already acted on this basis by integrating AI training and awareness initiatives into their governance frameworks since the provision became applicable in February 2025.

The issue with Art. 4 is largely about timing and enforcement. As the core operational requirements of the AI Act are delayed, enforcement of AI literacy obligations should follow the same logic. A **grace period aligned with the revised timelines for high-risk AI requirements** is necessary to ensure consistency and proportionality.

During this period, no additional instruments, guidance, codes of practice or reporting expectations should be introduced.<sup>19</sup> AI literacy should remain a principle-based, flexible obligation, implemented through existing organisational practices.

## Fully remove registration requirements

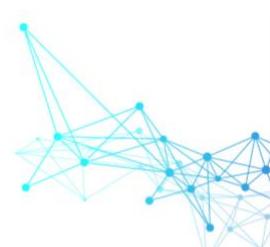
Under the AI Act, not all AI systems listed in Annex III qualify as high risk: whether they do depends on their intended purpose and context of use.<sup>20</sup> However, even where providers conclude that an Annex III system is not high risk, the Act still requires registration in the EU database. The AI omnibus would remove this inconsistency: providers would remain required to document their assessment and make it available to

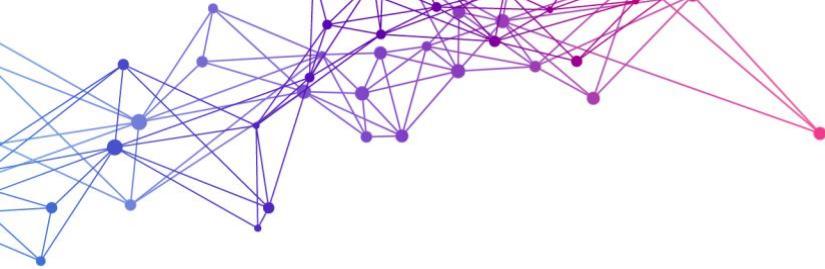
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<sup>18</sup> See DIGITALEUROPE, *AI in the workplace: Apply existing laws and build skills for the future*, available at <https://cdn.digitaleurope.org/uploads/2025/10/DIGITALEUROPE-AI-in-the-workplace-recommendations-October-2025.pdf>. As part of the ARISA project, DIGITALEUROPE worked with the Commission's AI Office to analyse AI literacy practices, provide insights into the practical application of Art. 4 and inform stakeholders of existing learning activities and programmes that they can leverage and implement themselves. See [https://aiskills.eu/wp-content/uploads/2025/11/FINAL\\_ARISA\\_REPORT-1.pdf](https://aiskills.eu/wp-content/uploads/2025/11/FINAL_ARISA_REPORT-1.pdf). The Commission should build on these learnings and on its Q&A and repository pages to further develop practical guidance on AI literacy. Such guidance could be periodically updated to incorporate feedback from industry and reflect technological developments.

<sup>19</sup> The omnibus proposal introduces language inviting the Commission and Member States to 'encourage' AI literacy measures. Whilst well intentioned, this creates uncertainty as to how such encouragement would materialise in practice. In the absence of clear limits, providers and deployers could be exposed to multiple, uncoordinated initiatives at EU and national level – such as guidance, codes of practice or other soft-law instruments – effectively reshaping an obligation of means into a fragmented and evolving compliance expectation.

<sup>20</sup> This is assessed through the so-called Art. 6(3) filter, which applies in particular where the AI system performs a narrow or preparatory task, supports or improves a prior human activity, detects patterns without influencing decisions or does not materially affect decision-making outcomes.





authorities upon request, but would no longer be obliged to register systems that fall outside the high-risk scope.<sup>21</sup>

Mandatory registration would nonetheless remain for other Annex III systems and for Annex I systems in real-world testing. This entails submitting highly sensitive information on AI systems, including their purpose, functionality, operating logic and deployment.<sup>22</sup> Public-sector deployers would also face registration and, in some cases, public disclosure obligations.<sup>23</sup>

Beyond administrative burden, this approach raises security and governance risks. Centralised databases of sensitive AI use cases – some publicly accessible – create attractive targets for malicious actors. These risks are compounded by parallel national databases for critical infrastructure, leading to fragmentation and uneven security standards.<sup>24</sup>

To avoid these risks and deliver genuine simplification, **mandatory AI system registration in high-risk EU database, as well as national databases, should be fully removed** by deleting Arts 49 and 71, whilst preserving documentation and supervisory powers for enforcement.

## Strengthen fair and impartial governance

The AI omnibus significantly strengthens the enforcement competences of the Commission's AI Office, particularly for AI systems based on general-purpose (GPAI) models, including the capacity to carry out pre-market conformity assessments. Moreover, the Commission might be empowered to monitor and supervise the compliance of all AI systems under the Digital Services Act,<sup>25</sup> when they are embedded in or constitute very large online platforms or search engines.<sup>26</sup>

Whilst an EU-level supervisory approach and governance can help generate more coherent enforcement, this harmonisation must be paired with a robust and credible governance framework. It should not lead to a scope expansion for the AI Act nor to additional burdens for businesses, and must fully align with national enforcement for similar AI systems.<sup>27</sup>

In its current form, the AI Office is responsible for drafting implementing acts and guidance whilst also interpreting and enforcing these same rules through investigations and sanctions. Concentrating both regulatory and enforcement tasks within a single body blurs roles, creates conflicts of interest and weakens the principle of good governance. Because the AI Office sits in DG CONNECT, within the Commission's

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<sup>21</sup> Art. 1(6), AI omnibus proposal.

<sup>22</sup> Section A, Annex VIII AI Act.

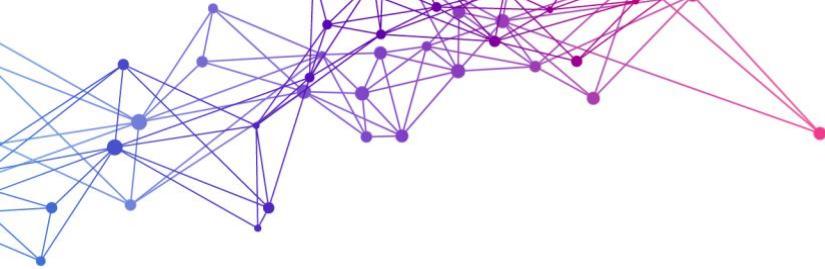
<sup>23</sup> Confidentiality only applies to points 1, 6 and 7, Annex III AI Act.

<sup>24</sup> Under Art. 49(5), high-risk AI systems used in critical infrastructure must be registered in national databases rather than the EU-level database. This mandates the creation of multiple national registries, introducing fragmentation and uneven security safeguards across Member States. This approach sits uneasily with the EU's broader objective of harmonising cybersecurity reporting and governance, including under the digital omnibus.

<sup>25</sup> Regulation (EU) 2022/2065.

<sup>26</sup> Art. 1(25), AI omnibus proposal.

<sup>27</sup> This issue is also relevant for the enforcement of transparency provisions under Art. 50, which may be enforced at national but also EU level via the future EU code of practice.



administrative structure, it may be exposed to political pressures that could affect the neutrality and consistency of enforcement.

To remedy these fundamental problems, the omnibus should **restructure the AI Office as a fully independent body** rather than a directorate within DG CONNECT.

## Include AI incident reporting in single entry point

The AI Act introduces standalone incident reporting obligations that will, in many cases, overlap factually with reporting duties under existing digital legislation, notably NIS2,<sup>28</sup> the GDPR and the Cyber Resilience Act.<sup>29</sup> In parallel, the digital omnibus establishes a single entry point for cyber and data incident reporting.<sup>30</sup>

To avoid hard-coding fragmentation at a moment where the EU is explicitly pursuing simplification, the AI omnibus should **explicitly recognise the single entry point as the primary reporting channel** once operational, and avoid maintaining parallel notification pathways that would undermine simplification efforts elsewhere in the EU digital framework.<sup>31</sup>

## Remove low-value ancillary obligations

Finally, to streamline cross-cutting provisions and avoid creating disproportionate burdens on innovators, particularly SMEs and startups and those relying on open-source development, as we proposed in our 2025 simplification recommendations, the AI omnibus should include additional proposals to amend the AI Act.<sup>32</sup>

This includes **deleting the AI Act's Art. 41 on common specifications**, which creates a parallel compliance route undermining public and private investment in harmonised standards. **Art. 82 on compliant AI systems 'which present a risk' should also be deleted**, as the power it grants national authorities to impose additional measures stems from overly broad and indeterminate provisions that will, if used, fragment the internal market.

Whilst we strongly support the **removal of the Commission-prescribed post-market monitoring template under Art. 72(3)**,<sup>33</sup> other related provisions could also be adjusted. Monitoring arrangements necessarily vary depending on the AI system, the deployment context and the deployer's requirements, and may involve confidential or security-sensitive processes. For this reason, **Annex IV(9) should not require a detailed description of the post-market monitoring system**. Art. 72, as well as future Commission guidance, should also explicitly recognise that deployers may restrict or oppose data and log collection for post-market monitoring purposes, limiting what providers can practically implement or document.

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<sup>28</sup> Directive (EU) 2022/2555.

<sup>29</sup> Art. 73 AI Act.

<sup>30</sup> Art. 6, digital omnibus proposal.

<sup>31</sup> The same outcome could be achieved by amending the AI Act through the digital omnibus to formally recognise the single entry point for incident reporting, in line with the approach taken for other digital legislation in that proposal. See DIGITALEUROPE's position on the digital omnibus proposal, available at <https://cdn.digitaleurope.org/uploads/2026/02/Digital-omnibus-a-first-step-and-what-must-come-next-now.pdf>.

<sup>32</sup> See DIGITALEUROPE, *Digital simplification package: Our AI recommendations*.

<sup>33</sup> Art. 1(24) AI omnibus proposal.

**Source code access provisions in Arts 74(13) and 92(3) should be removed**, as requiring access to proprietary source code creates significant cybersecurity and intellectual property risks, whilst offering little additional supervisory value compared to existing documentation and audit mechanisms under the AI Act.<sup>34</sup>

**Fundamental rights impact assessments (FRIAs) set in Art. 27 should be replaced with data protection impact assessments (DPIAs) under the GDPR** to avoid duplication and ensure coherence with well-established data protection processes. At the very least, the two regimes should be streamlined, for instance through a common baseline template and/or a unique assessment combining DPIA and FRIA into one single assessment for relevant high-risk AI systems, with overlaps removed.

Finally, to prepare for future simplification changes to the digital rulebook via the upcoming fitness check,<sup>35</sup> the **requirement to affix a CE marking to high-risk AI systems should be deleted** (Art. 48). This marking is ill-suited to purely digital technologies – it was designed for physical products, not software – and does not provide meaningful additional clarity for users or authorities.

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<sup>34</sup> Furthermore, these provisions infringe certain trade agreements signed by the EU. For instance, the EU-Japan Economic Partnership Agreement (Chapter 8, Art. 8.73) explicitly prohibits forced source code disclosure between the two regions.

<sup>35</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/15554-Digital-fitness-check-testing-the-cumulative-impact-of-the-EUs-digital-rules\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/15554-Digital-fitness-check-testing-the-cumulative-impact-of-the-EUs-digital-rules_en).

## About DIGITALEUROPE

DIGITALEUROPE is the leading trade association representing digitally transforming industries in Europe. We stand for a regulatory and investment environment that enables European digitalizing businesses across multiple sectors, as well as citizens, to prosper through digital technologies. We wish Europe to grow, attract and sustain the world's best digital talents, investment and technology companies. Together with our members, we shape the industry policy positions on all relevant policy matters, and contribute to their development and implementation. Our membership represents over 56,000 businesses who operate and invest in Europe. It includes corporations and scale-ups which are global leaders in their fields of activity, as well as national trade associations from more than 30 European countries.

