

Digital Omnibus on AI

Industrial AI must be viewed as an opportunity, not a risk.

23 February 2026

Executive Summary

The Digital Omnibus on AI offers an important opportunity to stabilise the implementation of the AI Act. However, without targeted adjustments, the proposal risks adding complexity instead of reducing it. BDI therefore calls for a sequenced, proportionate and industry-oriented refinement of the framework, prioritising legal certainty, predictable timelines and workable obligations.

1. Separation of Timeline decision and Timeline Extension. The lengthy ordinary legislative procedure risks undermining the proposal's core purpose on the extension of the timelines: enabling smooth, innovation-friendly standards implementation and restoring planning certainty for AI providers and deployers. To ensure the timeline provisions will have a substantial relief effect, we urge The EU Commission to split timeline changes from the broader AI Act Omnibus (points 30-31 plus corresponding recitals) and the parliament to fast-track its adoption. Additionally, the proposal for postponing high-risk requirements must establish a fixed postponement date rather than a dual mechanism that allows the Commission to unilaterally trigger delays and create additional planning uncertainty.

2. High-Risk Requirements (Annex I and Annex III). The current interplay between the AI Act and sectoral product legislation remains unresolved. Fragmented obligations, unclear conformity assessment pathways and overlapping requirements risk delaying market access. To restore coherence, **Annex I Sections A and B should be merged**, and AI-specific obligations integrated into sectoral regimes that already govern these products.

3. Notification and Conformity Assessment. The proposed adjustments do not yet deliver genuine simplification. Scope extensions must be possible through **gap assessments**, dependency on sectoral regulation for single application/single assessment must be removed, and **technology-based partial notifications** in Annex XIV Section 2(3) abandoned. The internal control procedure under Article 43(3) must remain **free from opt-outs** to safeguard internal market consistency.

4. Scope: Research, Development and Testing. Articles 2(6) and 2(8) require clear exemptions for research, development and testing, including **real-world testing prior to market placement**. Without such clarity, Europe risks constraining industrial and academic innovation and delaying safety-relevant model evaluation.

5. Transparency Obligations (Art. 50). Transparency requirements must be realistic, technically feasible and proportionate. BDI calls for a **12-month postponement** of Articles 50(2) and 50(4) and a clear confirmation that **Article 50(2) shall not apply retroactively**. Furthermore, transparency rules must reflect **B2B deployment realities** and avoid imposing consumer-level requirements on industrial use cases.

6. Remaining Structural Adjustments. Regulatory coherence between the AI Act and the GDPR must be ensured. Article 4a AI Act should align with the more flexible approach of Article 88c GDPR, which must **explicitly apply beyond the employment context**. Clarifications are needed regarding the legacy clause, the definition of adaptivity as a core AI characteristic, and that **intra-group deployment does not constitute placing on the market**.

Collectively, these adjustments are necessary to ensure that the Digital Omnibus fulfils its purpose: reducing complexity, increasing legal certainty and enabling a competitive, innovation-driven AI ecosystem in Europe.

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AI Act – Comments on proposed Amendments to Regulation (EU) 2024/1689

Article 1 (2) (g), Article 11 (1); Article 17 (2); Article 57 (5) (e); 70 (8); 99 (6) – Subject matter and Simplifications for SMEs

BDI welcomes the proposal to include simplifications for small mid-cap enterprises (SMCs) additionally to small and medium-sized enterprises, including start-ups.

Article 1(12) - Annex XIV (NANDO Codes)

The proposal to introduce granular NANDO notification codes via Annex XIV does not simplify the framework but adds unnecessary complexity. Highly specific codes for high-risk AI systems (e.g. AIH 0201 for structured-data systems or AIH 0205 for environment-learning systems) illustrate unclear definitions and ambiguous category boundaries. Such granularity risks undermining regulatory coherence and increasing administrative burdens for authorities, notified bodies and companies at a time when simplification is urgently needed.

BDI therefore does **not** support the introduction of narrowly tailored product-type codes. Instead, BDI recommends maintaining the current horizontal notification structure until harmonised AI standards are finalised. Introducing new code systems before standardisation is complete would only increase uncertainty and workload without adding regulatory value.

Article 2(6) and 2(8) – Research and Development Exemption and Testing under Real-World Conditions

BDI calls for a coherent clarification and expansion of the exemptions laid down in Articles 2(6) and 2(8). The current wording does not sufficiently reflect the realities of scientific and industrial AI development. In particular, the exemptions must also apply where AI systems or AI models are placed on the market, put into service, or used exclusively for scientific research, development or testing purposes, including testing under real-world conditions prior to market placement.

For this reason, we propose the following adjustment:

“This Regulation does not apply to AI systems or AI models, including their output, insofar as they are placed on the market, put into service or used solely for the purpose of scientific research and development.”

A clear and comprehensive exemption is essential to avoid hindering research activities and to ensure that academic and industrial research environments in Europe remain globally competitive.

Article 10/ New Article 4a - Processing of special categories of personal data for bias detection and mitigation

Paragraph 5 introduces a new Article 4a, replacing Article 10(5) AI Act, which provides a legal basis for providers and deployers of AI systems and AI models to exceptionally process special categories of personal data for the purpose of ensuring bias detection and correction under certain conditions. The change is welcomed, but some clarification regarding anonymisation and pseudonymisation might be warranted. High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2, 3 and 4 of this Article and in Article 4a(1) whenever such data sets are used. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.

Article 28 (8), Article 29 (4) – Notifying authorities

BDI welcomes the streamlining of the notification procedure as proposed.

Article 49 (2) – Registration

BDI welcomes the proposal to exclude providers of AI systems from the obligation to register, if the AI system has been deemed not to be high risk according to Article 6 (3).

Article 57 and 58 – AI regulatory sandboxes

BDI welcomes the possibility for the AI Office to establish a regulatory sandbox. Furthermore, BDI welcomes the proposed amendments which put a stronger emphasis on the cross-border cooperation between national competent authorities surrounding regulatory sandboxes.

Article 69 (3) – Access to the pool of experts by the Member States

Ensuring a timely access to the pool of experts is of great importance. Deleting Article 69 (3) without replacement could provide a barrier to a harmonized enforcement. For this reason, BDI rejects the deletion of Article 69 (3).

Additional Amendments necessary | What's Missing?

Separate the postponement from the rest of the proposal and postpone the high-risk requirements 24 months

The Commission's proposal to postpone high-risk requirements is a step in the right direction but remains insufficient. The suggested postponements (up to 16 months for Annex III systems and up to 12 months for Annex I A systems) cannot be adopted in time through the ordinary legislative procedure. The lengthy negotiation cycles of past EU legislation demonstrate that a timely decision is unrealistic, leaving providers and deployers with only a few months before obligations enter into force in August 2026.

To ensure that the mechanism can be adopted swiftly, BDI calls for separating the timeline adjustments from the rest of the Omnibus and fast-tracking them through simplified parliamentary procedures. A standalone proposal would allow urgent adoption of points 30 and 31 and their recitals, while the remaining Omnibus provisions could proceed at normal pace.

Substantively, the proposed postponements do not reflect the scale of implementation challenges. Companies will depend on up to 35 harmonised standards, each of which requires significant time for development and internal adoption. Even a single standard typically requires at least 12 months to implement. A transition period of only six months between finalisation of standards and applicability of Annex III requirements would slow product releases, reduce investment and undermine innovation. The dual timeline mechanism, which can be triggered unilaterally by the Commission, further reduces planning certainty.

To ensure workable implementation, BDI calls for a 24-month extension of all high-risk requirements under Annex I and Annex III, including a corresponding 24-month deferral of fines for non-compliance.

Integrate high-risk requirements related to Annex I A into sectoral legislation

Early implementation experience shows the limits of applying horizontal AI rules to established sectoral frameworks, particularly those under Annex I Section A. The development of harmonised AI standards is progressing more slowly and with greater complexity than anticipated, leaving manufacturers uncertain about how new AI-specific standards will align or conflict with existing sectoral requirements. This ambiguity risks creating bottlenecks and destabilising long-standing compliance pathways.

The challenge is especially acute in conformity assessment. Notified bodies in highly regulated sectors such as automotive, machinery and medical devices are already operating at capacity. Adding AI-related obligations without a clear integration pathway could compound delays and disrupt market access, disproportionately affecting sectors where Europe holds global competitive advantages.

For these reasons, **Annex I should be streamlined by merging Sections A and B and applying the more flexible Section B logic across the entire annex.** This approach would allow AI requirements to be incorporated progressively into sectoral frameworks, ensuring that harmonised AI standards can be embedded into existing systems without undermining established conformity procedures.

Integration must follow a sequenced approach grounded in existing legislation. The objective is not to reopen functioning regulatory systems, but to align them with the AI Act in a way that preserves legal certainty. To achieve this, the simplification package must clarify the AI Act's role as a maximum-harmonisation instrument: sector-specific measures, whether delegated acts, implementing acts or technical specifications, must not introduce requirements beyond the AI Act. This is essential to prevent inconsistent obligations and to maintain a unified understanding of the 'state of the art' across sectors.

Avoid unnecessarily burdensome notification processes

We welcome the Commission's intention to simplify the notification procedure for conformity assessment bodies. In its current form, however, the proposal does not achieve this goal and leaves important questions unresolved, particularly for bodies already notified under sectoral legislation.

A key gap concerns scope extensions. Although the draft refers to a single application and assessment procedure, it does not clearly state that existing notifications may be expanded through an AI-related gap assessment. Instead, the wording suggests that already-notified bodies may be required to undergo a full new notification process. This would contradict the objective of simplification and delay the availability of notified bodies for high-risk AI systems.

BDI also stresses that the internal control procedure under Article 43(3) must not be subject to optional deviations. Allowing exceptions would weaken the coherence of the conformity assessment system and create uncertainty for companies operating across multiple Member States. A uniform approach is essential for maintaining confidence and consistency in the internal market.

BDI therefore recommends three adjustments:

1. Establish a clear and straightforward process for extending existing sectoral notifications through a gap application and gap assessment.
2. Remove the dependency on sectoral legislation for the availability of a single application or single assessment procedure.
3. Delete technology-based partial notifications in Annex XIV Section 2(3) to avoid unnecessary fragmentation.

Postponement of transparency obligations of 12 months must apply for both providers and deployers of GPAI-systems

No harmonised standards will be available for the transparency obligations under Article 50 of the AI Act. The Commission has begun drafting guidance and a code of practice, but these will not be finalised before May or June 2026, leaving only a few weeks before the rules apply. The Omnibus therefore proposes a six-month enforcement delay for certain obligations for legacy generative AI systems placed on the market before 2 August 2026, specifically those under Article 50(2), which require providers to mark AI-generated outputs.

However, no grace period is given to AI deployers that need to disclose AI-generated content as such, even though AI-marking may not be available at that time. For consistency, the proposed grace period should also cover Art. 50(4) and be extended to 12 months, to ensure that providers and deployers have sufficient time to analyse and implement the code of practice.

Moreover, the restriction of the grace period to 'systems placed on the market before 2 August 2026' creates an unworkable compliance gap. Providers and deployers will lack adequate time to align systems entering the market immediately after this date with the code of practice before requirements take effect. This could severely delay market entry for many generative AI systems planned to launch shortly after 2 August 2026, thereby distorting the market. The restriction to 'systems placed on the market before 2 August 2026' must therefore be removed.

Certain provisions of Article 50 will not be addressed by the code, but only via guidelines, including provider and deployer information obligations to natural persons either interacting with the AI or exposed to it. As these guidelines are also only expected just before the summer 2026, the grace period

should also cover AI providers and deployers in scope of Art. 50(1)-(3), so that they have enough time to adapt their AI systems. BDI further calls for **clarity regarding Article 50(7)**. Transparency requirements must be proportionate in B2B contexts. In industrial environments, transparency is already ensured through contractual obligations, documentation and established processes among professional operators. The regulation should explicitly recognise this and avoid imposing consumer-facing transparency requirements on purely B2B use cases.

Adaptivity as an Essential AI Characteristic

BDI proposes clarifying in Article 3 that adaptivity constitutes an essential characteristic of AI systems. This includes the capacity of an AI system to adjust parameters or behaviour in response to environmental changes or new input data.

A clear definition is necessary to ensure consistent interpretation across sectors and to distinguish AI systems from static software components governed by existing product legislation.

Enshrine the legacy clause clarifications into the operative provisions

Recital 21 provides important clarification on the legacy clause in Article 111(2). It confirms that once an AI system has been placed on the market or put into service before the high-risk requirements apply, all units of the same type and model benefit from the legacy clause, including those placed on the market afterwards. It also confirms that substantial modifications trigger renewed compliance obligations for both future units and those already in use.

These clarifications are necessary because the concept of an “individual product unit” does not fit AI systems, which are often distributed as software through continuous update channels. In sectors with long development and certification cycles, market placement must be understood at model or type level rather than for each single unit.

To ensure legal certainty, the clarifications made in Recital 21 should be incorporated into the operative text of Article 111. This would also help address potential inconsistencies with NLF legislation under Annex I, which follows a different logic for placing products on the market.

In addition, the AI Act should harmonise the terminology around “substantial change” and “substantial modification” to ensure consistent interpretation throughout the Regulation and avoid diverging legal outcomes.

Remove the Fundamental Rights Impact Assessment from the AI Act

Art. 27 requires providers of high-risk AI systems to conduct fundamental rights impact assessments (FRIAs). These assessments evaluate how the AI system itself may impact individuals' fundamental rights, including human dignity, non-discrimination, and freedoms protected under the EU Charter. At the same time, Art. 35 GDPR requires data protection impact assessments (DPIAs) to assess how the processing of personal data may affect individuals' rights and freedoms.

Whilst the two assessments seem to differ in focus – FRIAs assess the AI system, whilst DPIAs assess personal data processing – in practice they cover practically the same concerns. Conducting both assessments would lead to redundancy and obviously increase the compliance burden for public authorities and companies in scope, while not meaningfully contributing to better protection of fundamental rights.⁴

Therefore, we suggest removing Article 27 from the AI Act.

Align legal bases with the GDPR

The AI Omnibus introduces a new Article 4a to provide a legal basis for the exceptional processing of special categories of personal data for bias detection and mitigation. While we support the intention, the provision does not add substantial clarity compared to Article 10(5). Its main effect is to extend the scope from high-risk providers to high-risk deployers and to providers and deployers of other AI systems. Beyond that, the legal framework remains fragmented.

At the same time, the Commission's Digital Omnibus proposes amendments to the GDPR, including a new Article 88c that would allow the processing of personal data for the development and operation of AI systems on the basis of legitimate interest. This approach is more flexible than the AI Act and creates a risk of inconsistency between the two instruments. Alignment is therefore necessary. A clear and streamlined version of Article 88c should form the basis for revising Article 4a of the AI Act; otherwise, companies and public bodies may avoid using personal data needed to improve AI systems, weakening the effectiveness of bias-mitigation measures.

It must also be made clear that Article 88c is not limited to processing employee data. Restricting it to the employment context would not reflect industrial AI practice and would unnecessarily limit the lawful use of customer and operational data for development, testing and quality assurance.

Making an AI system available to other entities in the same corporate group does not constitute a 'placing on the market'

Clarification that entity does not become a provider of an AI model merely by making it available to other entities within the same corporate group (in the definition of "provider" in Article 3(3) or "placing on the market" in Article 3(9) AI Act).

We would welcome the inclusion of a definition of 'user' of an AI system as a negative demarcation. This definition should also be understood as broadly as possible and refer to AI systems that are 'deployed in non-product-related contexts.

Mediating role of the AI Office in case of diverging interpretation between member states

The competencies of the AI Office should be extended to include the resolution of inconsistencies between national supervisory authorities. Since AI deployment can occur EU-wide, differing interpretations by supervisory authorities are likely. However, no escalation mechanism currently exists. The AI Office, as a 'supervisory authority' overseeing supervisory authorities, should be granted a mandatory mediating function within a three-month period so that disputed legal questions can be resolved. After attempting clarification with national authorities, affected providers or operators should also have the right to escalate matters to the AI Office

Clarification and removal of specific application areas from Annex III

A review of Annex III is needed to clarify and, where appropriate, remove specific application areas. The Commission should make active use of the procedures under Article 6(6) and (7) and Article 7(3). As an immediate step, the guidelines should clarify that risk assessments in life and health insurance under Annex III(5)(c) that do not influence pricing, or the selection of policyholders are generally not considered high-risk.

Further clarification is also required for Annex III(5)(a). As currently drafted, there is a risk that AI systems used for purely organisational tasks in the healthcare sector, such as managing bed allocation or other administrative planning, could be interpreted as falling under the high-risk definition. Since such systems do not create material risks for fundamental rights, the provision should make clear that organisational and administrative functions are excluded. This can be achieved by removing the word "grant" and adding an explicit exclusion for organisational services such as billing and inventory management.

The provision should therefore read:

“AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services, as well as to reduce, revoke or reclaim such benefits and services, excluding organisational services such as billing and inventory management.”

Article 11 and Annex IV

The requirements concerning documentation as set out in Article 11 and Annex IV remain too extensive. While BDI welcomes the addition of SMEs to the simplification, German industry reiterates its proposal to simplify the documentation requirements for high-risk AI systems in general. Additionally, templates should be provided that are based on examples. The use of templates should be mandatory if no personal data is involved

Article 51 and 54 – General Purpose AI

The threshold value for GPAI pursuant to Art. 51 II AI Act has not been adjusted. German industry proposes revising the thresholds for systemic risk in GPAI models to be more flexible and based on actual risk not addressed in other regulation rather than arbitrary numbers.

Imprint

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EU Transparency Register: 1771817758-48

German Lobbyregister: R000534

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Document number: D 2205