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A BSI position paper

BSI Group recommendations for the AI omnibus

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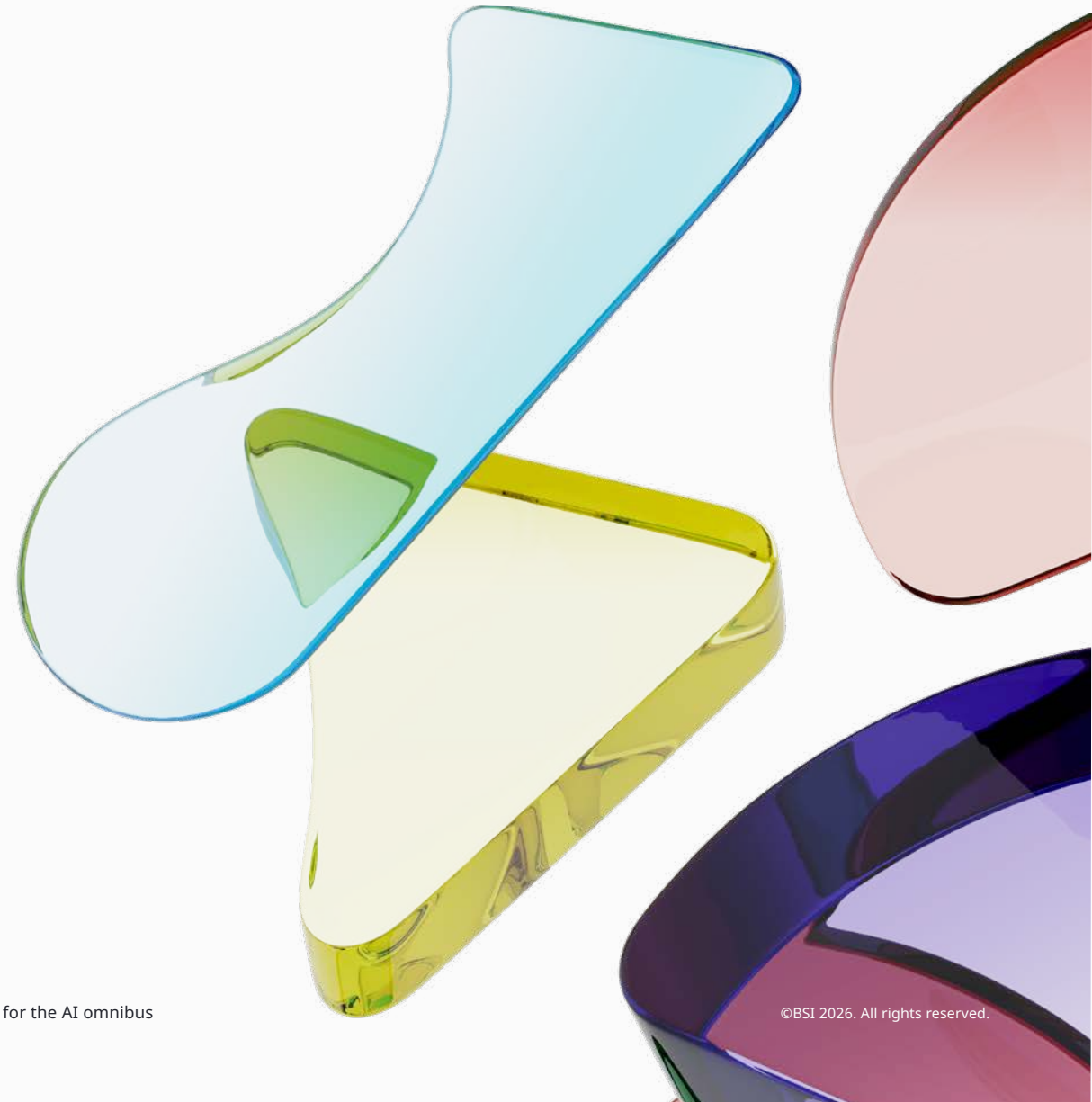

Introduction

BSI Group is providing this position paper in response to the European Commission's AI Omnibus proposal. Our objective is to highlight potential impacts on the operations, capacity, and effectiveness of notified bodies, and to provide constructive recommendations to ensure that the AI Act remains workable, consistent, and aligned with existing regulatory frameworks.

BSI Group is a global organisation providing independent conformity assessment, testing, certification, and regulatory services to support safe and compliant market access worldwide. With over 30 years of experience as a full-scope EU Notified Body, UK Approved Body, MDSAP Auditing Organisation, ISO 13485 Certification Body, and Registered Certification Body for the PMDA, BSI supports conformity assessment in more than 12 countries. Through its Notified Body (NB 2797), BSI delivers rigorous third-party assessments across multiple regulated sectors.

Removal of dataset testing for Annex I Section A products

The AI Omnibus amends Article 43 (3) on how high-risk AI systems that are part of products regulated under existing Union harmonisation legislation (Annex I, Section A) are assessed. Under the revised text, these systems continue to follow the conformity assessment procedures of the relevant sectoral legislation, while also applying the AI Act requirements. The assessment of the AI Act quality management system under Article 17 and Annex VII still applies.

However, the Omnibus removes the references to points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII related to the assessment of training, validation and testing datasets. As a result, notified bodies assessing Annex I Section A products will no longer be allowed to review or test datasets as part of the conformity assessment.

This change means that independent third-party oversight of dataset-related risks for these Annex I Section A high-risk AI systems will be more limited. **Without the possibility for notified bodies to review and test datasets there is a risk that systemic issues such as bias, data gaps or inappropriate data use may go undetected, particularly in sectors where AI outputs can directly affect health, safety or fundamental rights.** Maintaining an appropriate level of third-party scrutiny over dataset-related risks is therefore essential to preserve trust and ensure that AI Act safeguards remain effective in practice.

Recommendation:

Restore in Article 43(3) the references to points 4.3, 4.4, 4.5 and the fifth paragraph of point 4.6 of Annex VII, so that notified bodies can assess the training, validation and testing datasets for Annex I Section A high-risk AI systems.

Single application and assessment procedure for Notified Bodies

Article 28(8) aims to simplify the designation process for notified bodies by allowing a single application and a single assessment for designation under both the AI Act and sectoral legislation listed in Annex I, Section A (such as medical devices, in vitro diagnostics, machinery, or radio equipment). This objective is welcome, as it could reduce duplication, shorten designation timelines, and support a faster build-up of notified body capacity for AI systems.

Article (28) also states the possibility to submit a single application for designation "where the relevant Union harmonisation legislation provides for such single application and single assessment procedure". However, in some of the sectorial legislations covered in AI Act Annex I section A, there is no such option. For example, the Medical Devices Regulation's Article 38(2) clearly states that in the application for designation "shall specify the conformity assessment activities as defined in this Regulation".

While the proposal allows notified bodies to reuse existing designation documentation and certificates obtained under sectoral legislation (Article 29(4)), in practice this reuse may be limited for the following reasons:

- Conformity assessment under the AI Act, found in Annex VII, differs significantly from routes to conformity under sectoral laws. AI conformity assessments focus on issues such as datasets testing and validation, data governance, bias, AI logs, human oversight, post-market monitoring during the AI lifecycle etc., areas not fully addressed under existing sectoral designations. As a result, notified bodies must demonstrate new competences, procedures, and capabilities specific to AI.
- AI Act Article 31 introduces additional requirements to notified bodies, not to be found in other sectorial legislations. Some of the additional requirements dictated in AI Act are: Article 31(11) on competence of personnel, including legal personnel, Article 31(12) coordination activities, Article 31(2) cybersecurity requirements, and testing capabilities (Annex VII, points 4.3, 4.4, 4.5 and fifth paragraph of point 4.6)

Therefore, to ensure harmonisation of notified bodies designated under the AI Act, it is important to emphasise that the single application and reuse of documents and certificates (Article 29, par. 4 of Omnibus proposal), should not override the AI Act requirements for notified bodies. Article 29, paragraph 4, in the last paragraph supports this argument by stating "monitor and verify continuous compliance with all the requirements laid down in Article 31". However, the emphasis is on already designated notified bodies under other Union harmonisation legislation, and reference to Article 31 excludes Annex VII requirements as stated in Annex VII section 4.4: "the notified body **shall itself directly carry out adequate tests**, as appropriate".

Article 43(3) second paragraph, states that notified bodies already designated under sectoral legislation shall assess high-risk AI systems if their compliance with Article 31(4) independence, (5) impartiality, (10) integrity and (11) competent personnel has been assessed in the context of sectoral notification. For independence, impartiality and integrity, sectoral requirements are similar and have been already assessed. However, Article 31(11) on competent personnel raises practical questions. For example, an MDR notified body was assessed for staff competent to assess medical devices, not AI-specific risks or systems. The AI Act introduces new competences that were not part of the original sectoral designation, because AI Act did not exist at the time.

At the same time, the AI Omnibus introduces a requirement in Article 43(3) for those notified bodies to apply for designation under the AI Act within 18 months. However, the text does not clearly specify which activities sectoral notified bodies may perform during those 18 months, nor whether authorities may still require a full AI Act designation even within the 18 months' timeframe.

More broadly, imposing a fixed deadline for AI Act designation may limit the ability of notified bodies to plan their activities based on actual demand, capacity and strategic priorities. Notified bodies need sufficient flexibility to build AI-specific expertise without being forced into premature or rushed designation processes that could strain resources and affect assessment quality.

BSI Group recognises that notified bodies designated under sectorial law will ultimately need to be designated under the AI Act in order to carry out AI Act conformity assessments. **However, this designation should be treated as scope extension, not as a full re-designation**. Existing notified bodies have already demonstrated compliance with core requirements such as independence, impartiality, integrity, governance and documented procedures, and have long-standing experience in complex conformity assessment activities. These elements should be recognised as a baseline.

AI Act designation should therefore focus on demonstrating **AI-specific competences**, including the relevant competency codes introduced by the AI Omnibus in Annex XIV and the ability assess training, validation and testing datasets in line with Annex VII. Assessing only these additional elements would avoid unnecessary duplication, reduce administrative burden for notifying authorities and notified bodies, and support a faster and more consistent build-up of notified body capacity under the AI Act.

Recommendations:

- Clarify how under Articles 28(8) and 29(4) the notified bodies designated under the Union harmonisation legislation listed in Section A of Annex I, can apply for designation with existing documentation, while satisfying AI Act Article 31 and Annex VII requirements on testing datasets and AI models.
- Clarify how Article 28(8) and Article 43(3) should operate in practice, including what activities sectoral notified bodies may perform during the 18-month period prior to AI Act designation.
- Treat AI Act designation for already-notified sectoral bodies as a scope extension, not a full re-designation.
- Provide clear guidance to notifying authorities to ensure consistent application across Member States and avoid duplication.
- Ensure sufficient flexibility in designation timelines to allow notified bodies to build AI expertise in a structured and sustainable way.

Role of Notified Bodies in GPAI Assessments

Article 75.1c proposes to give the AI Office exclusive responsibility for the supervision and enforcement of certain AI systems based on general-purpose AI (GPAI), excluding systems covered in Annex I. The AI Office is also entrusted with this responsibility for AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine.

For high-risk AI systems falling under this scope and subject to third-party conformity assessment, the Commission would organise and carry out pre-market conformity assessments and tests. The proposal further states that the AI Office "may entrust" these assessments to notified bodies designated under the AI Act, with notified bodies acting on behalf of the Commission.

This provision has the potential to create a new and important role for AI notified bodies. Notified bodies have long-standing experience in performing independent, technical conformity assessments under EU product legislation. They operate under strict requirements of independence and impartiality and have established methodologies for complex technical assessments. Involving notified bodies in GPAI assessments could therefore strengthen oversight, improve scalability, and support consistent enforcement across the EU.

However, the proposal lacks clarity on how this mechanism will work in practice.

First, the role of notified bodies in this process is not clearly defined. It is unclear whether they would perform a full conformity assessment equivalent to Article 43 procedures, whether they would conduct specific technical tests only, or whether they would act as technical advisors to the AI Office. The legal status of the outcome is also uncertain. It is not specified whether a positive assessment would lead to CE marking, replace or complement an Article 43 certificate, or constitute a separate authorisation decision by the Commission.

Second, the proposal does not clarify how notified bodies would be selected when entrusted with assessments. Given that multiple notified bodies may be designated under the AI Act across different Member States and sectors, transparent

criteria and procedures for selection will be necessary to ensure equal treatment, avoid fragmentation, and preserve trust in the system.

Third, Article 75.1c refers to pre-market conformity assessments for high-risk AI systems, which appear to verify compliance before placing the system on the market. This raises important questions regarding the interaction with Article 43, which already establishes conformity assessment procedures for high-risk AI systems. Without clarification, there is a risk of duplication, parallel assessments, or inconsistent outcomes between Commission-led procedures and notified body conformity assessments under Article 43.

The proposal also raises questions about capacity and resourcing. The AI Office is still in the process of becoming fully operational. Adding direct responsibility for pre-market conformity assessments of complex and highly technical GPAI systems will require significant additional expertise and resources. A structured and predictable involvement of notified bodies could mitigate the risk of bottlenecks, delays, and legal uncertainty for providers.

A clearer and more structured model is therefore needed. Third-party conformity assessment should not be treated as an ad hoc option, but as a core part of GPAI oversight. **Notified bodies should carry out independent technical conformity assessments, while the AI Office focuses on coordination, consistency, and enforcement oversight.** This separation of roles would strengthen checks and balances and enhance legal certainty.

Recommendations:

- Clearly define the role of notified bodies under Article 75(1c), including whether they perform full conformity assessments, specific testing activities, or advisory functions. Clarify the legal status and effect of assessments performed on behalf of the Commission, including their relationship with CE marking and Article 43 conformity assessment certificates.
- Establish transparent and objective criteria for selecting notified bodies entrusted with GPAI assessments.
- Ensure coherence between Article 75.1c and Article 43 to avoid duplication or parallel conformity assessment procedures.
- Embed notified body involvement as a structured and predictable element of GPAI governance, rather than a discretionary or ad hoc option.

Harmonised standards and application dates

BSI Group is concerned about the proposal to link the applicability of AI Act obligations to the availability of harmonised standards. The use of harmonised standards is voluntary, and their development timelines are uncertain. Making the application of legal obligations conditional on their availability risks creating significant legal and operational uncertainty for providers, authorities and notified bodies.

While we recognise the real implementation challenges faced by Member States, any postponement of the AI Act should remain strictly limited in time and clearly defined. Open-ended or conditional delays risk prolonging uncertainty and weakening confidence in the regulatory framework.

Delaying the application of the AI Act also delays the implementation of essential safeguards for high-risk AI systems. As a result, consumers and users remain exposed for longer to risks related to transparency, accountability and fundamental rights, without the protections foreseen by the AI Act.

Delayed applicability also slows the effective mobilisation of notified body capacity. BSI Group is already investing in AI expertise, procedures and technical capabilities to support compliance with the AI Act. Prolonged uncertainty about when obligations apply risks discouraging investment, fragmenting preparedness across Member States, and ultimately delaying the availability of notified bodies when the AI Act becomes applicable.

BSI Group therefore supports the introduction of clear “hard backstops” for the application of high-risk requirements. Fixed dates provide a common planning horizon, enable investment decisions, and allow notified bodies to scale capacity in a predictable way.

Recommendations:

- Do not link the applicability of AI Act obligations to the availability or application of harmonised standards, given their voluntary nature and uncertain timelines. Standards should support compliance, not delay it.
- Keep any postponement of AI Act obligations strictly limited in time and clearly defined, avoiding open-ended or conditional delays.

Integrity of Annex I and the New Legislative Framework

BSI Group notes that proposals have been tabled in the European Parliament to move the legislations listed in Annex I Section A to Section B of the AI Act.

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Such a change was not part of the AI Omnibus proposal but originates from discussions in the context of the MDR/IVDR simplification. Transferring these legislations to Section B would fundamentally alter the horizontal logic of the AI Act and weaken its alignment with the New Legislative Framework. In particular, it would reduce the role of harmonised standards and notified bodies, increase reliance on future sector-specific amendments by the Commission, and risk regulatory fragmentation and legal uncertainty.

BSI therefore considers that the structure of Annex I should remain unchanged to preserve coherence, predictability, and the integrity of the existing conformity assessment system.

Recommendation:

- Maintain the current structure of Annex I and refrain from moving Section A legislations to Section B, in order to preserve the horizontal nature of the AI Act.

Conclusion

BSI Group welcomes the AI Act's objectives to ensure safe and trustworthy AI but stresses that notified bodies play a critical role in delivering independent, technical oversight. To safeguard legal certainty, scalability, and effective implementation, BSI recommends clarifying the role of notified bodies, preserving assessment of training, validation and testing datasets, maintaining existing Annex I structures, and avoiding conditional delays tied to harmonised standards. These measures will strengthen AI governance, protect end-users, and enable notified bodies to contribute effectively to the regulatory framework.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

BSI Assurance UK Ltd (0086)

Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)

Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

BSI Group America Inc.

150 Opportunity Way,
Suite 900
Reston, VA 20190
USA

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn