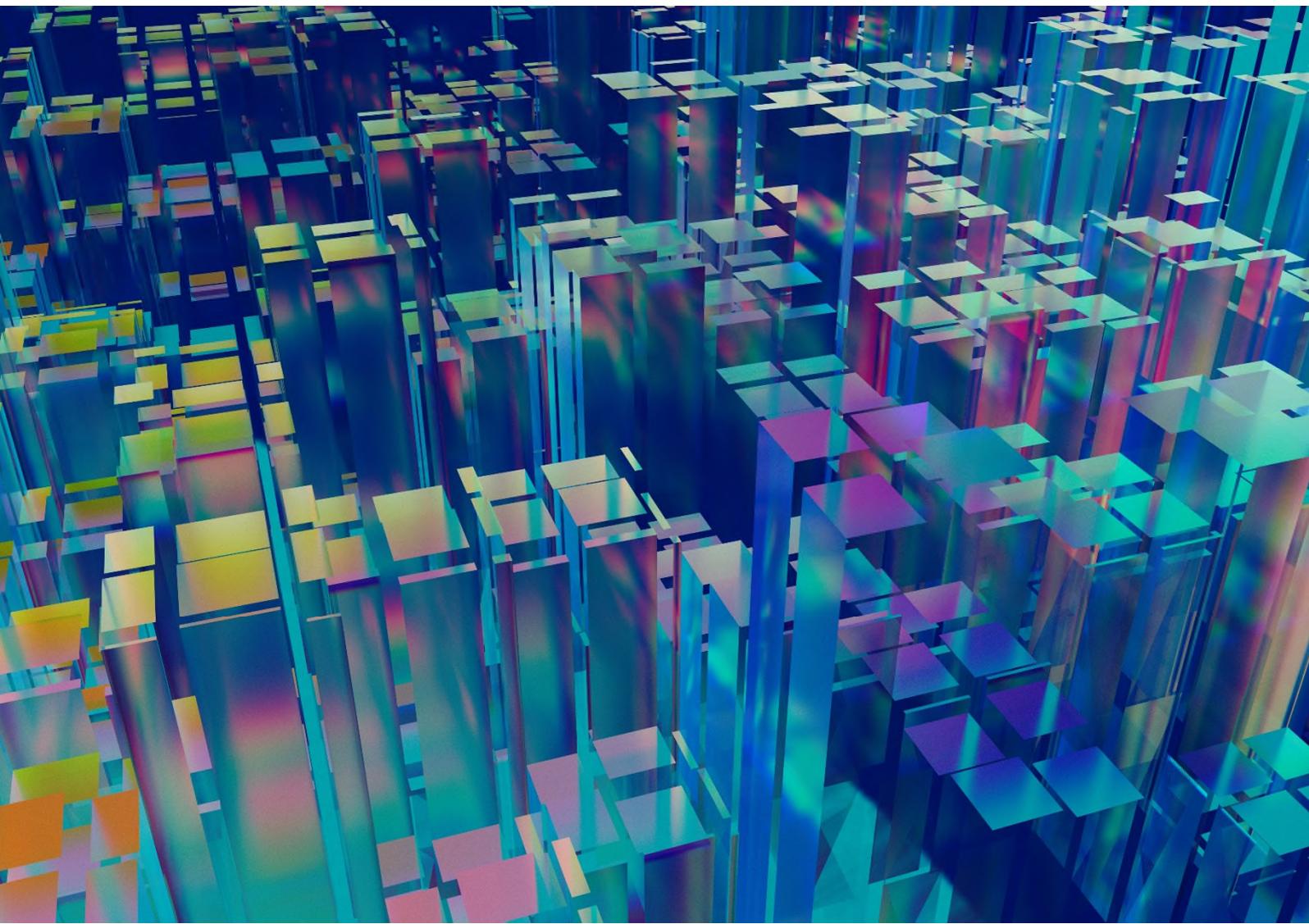


Position on the EU Commission's proposal (COM(2025) 836)

# Digital Omnibus on AI



## General remarks

The European Regulation laying down harmonized rules on artificial intelligence (EU) 2024/1689 (AI Act) created a groundbreaking legal framework for AI systems. As part of the digital package to simplify digital legislation ("Digital Omnibus"), the EU Commission proposed targeted amendments to the AI Act on 19 November 2025. In doing so, it addresses key implementation hurdles such as the ambitious implementation deadlines in view of the delay in developing standards, as well as unclear procedures for the designation of conformity assessment bodies.

The TÜV Association welcomes the EU Commission's initiative to make targeted adjustments with the Digital Omnibus in order to create a higher degree of legal certainty and to simplify the practical implementation of AI Act. The clarifications proposed by the EU Commission are a step in the right direction, but require further specification, particularly with regard to the designation procedures to be applied for conformity assessment bodies. It must be ensured that any simplifications do not lead to a de facto reduction in the high level of protection.

It is crucial to note that the Digital Omnibus alone cannot overcome all implementation hurdles; rather, it is one of many instruments that should be utilized in the implementation of the AI Act. The EU Commission still must ensure legal certainty through binding guidelines, accelerated standardisation processes, and implementation requirements. At the same time, the time window gained by postponing application deadlines must be used at the national level to set up designating and market surveillance authorities as quickly as possible and to establish testing structures on time.

## Key recommendations

### 1. Deadline extension: Use the time gained to establish national assessment structures

The TÜV Association welcomes a moderate postponement of the application deadlines for high-risk AI systems. The extended transition periods should be used primarily to establish national market surveillance and testing structures and to quickly and practically designate conformity assessment bodies. In addition, the EU Commission's foreseen guidelines and implementing acts must be published as soon as possible.

### 2. Enable mandatory scope extension for notified bodies

We welcome the goal of simplifying designation procedures as a critical implementation path, but still see unresolved issues. Existing designations under sectoral product legislation should be used as a basis and extended to include AI-specific competency requirements (scope extension). Time-consuming redesignations, additional bureaucracy for assessment bodies, and related higher costs for industry should be avoided.

### **3. Delete technology-specific designation codes (AIH codes)**

The TÜV Association welcomes the inclusion of designation codes in the AI Act, but rejects the introduction of technology-specific AIH designation codes in Annex XIV (point 2.3 (a-d)). These contradict the technology-neutral and application-based approach of the AI Act, cannot be clearly defined in technical terms, and would only lead to additional bureaucracy and time expenditure in the designation of testing bodies.

### **4. Simplify technical documentation for SMEs/SMCs with a sense of proportion**

The extension of the possibility to use a simplified technical documentation from SMEs to small mid-cap companies (SMCs) should be supported in principle. However, simplifications should be purely formal in nature and must not lead to reduced transparency and thus to less safety and higher risks for users. Notified bodies must continue to be able to comprehensively assess the conformity of technical documentation.

### **5. Ensure legally secure GPAI pre-market conformity assessments**

The proposed establishment of pre-market conformity assessments for particularly powerful general-purpose AI models (GPAI) is to be welcomed. However, the empowerment by the EU Commission to carry out these assessments by its own represents a clear departure from the established EU quality infrastructure. Such conformity assessments should be established with a sound legal basis, utilizing the expertise of notified bodies rather than creating duplicate structures.

### **6. Establish AI regulatory sandboxes at EU level, but not as a substitute for conformity assessments**

The TÜV Association welcomes the proposal to establish an AI regulatory sandbox at EU level (within the AI Office), as well as to extend real-world testing to Annex I products (e.g. automotive). However, it should be clarified that participation cannot automatically lead to a presumption of conformity. A complete conformity assessment, possibly involving a notified body, is still required before placing the AI system on the market.

## Key recommendations in detail

### 1. Deadline extension: Use the time gained to establish national assessment structures

Despite considerable political pressure, the EU Commission has opted for only a moderate postponement of the application deadlines. The proposal links the entry into force of high-risk AI system requirements (Chapter III, Sections 1–3) to the existence of adequate measures to support compliance (“stop-the-clock”). These include, in particular, the publication of harmonised standards with a subsequent implementation period of 6 months (for Annex III AI systems) or 12 months (for Annex I AI systems). Should the publication of standards be further delayed, maximum transition periods are also provided for this scenario – 2 December 2027 for Annex III AI systems and 2 August 2028 for Annex I AI systems.

The TÜV Association welcomes the decision to postpone the application deadlines by a maximum of 16 months. A timely transition period is necessary in order to adequately address the risks posed by AI systems to health, safety, and fundamental rights, and to avoid jeopardizing Europe's leading role as a place for safe and trustworthy AI systems. The proposed maximum deadlines also give all economic operators legal and planning security. Nevertheless, it should be emphasized that the expected delay in the availability of harmonised standards is not in itself a sufficient reason to justify a postponement. Just like EU product legislation as a whole, the AI Act provides for the possibility of placing AI systems on the market with the involvement of notified bodies, even without harmonised standards.

All stakeholders are called upon to use the time now gained to consistently drive forward the relevant processes and infrastructures necessary for successful implementation. From the perspective of the TÜV Association, this applies in particular to the rapid establishment of national market surveillance and assessment structures and the timely designation of conformity assessment bodies. The EU Commission is urged to closely monitor and promote the ongoing development of personnel and expertise in national AI supervisory structures, in particular the notifying authorities.

At EU level, there is now an urgent need for the timely publication of guidelines, templates and implementing acts that sufficiently specify the requirements of the AI Act. This applies in particular to uniform and enforceable notification criteria and procedures on the basis of which the national notifying authorities can carry out their accreditation or notification. Existing standards should also be used for this purpose, e.g., ISO/IEC 17065 (requirements for certification bodies for products, processes, services) and ISO/IEC 42001 (AI management systems).

#### Our recommendations:

- Use of the transition period for the targeted ramp-up of national AI supervisory and assessment infrastructure, supported by the EU Commission
- Timely publication of guidelines, templates and implementing acts, particularly with regard to notification criteria and procedures, using internationally compatible standards (including ISO/IEC 17065, ISO/IEC 42001) as a reference

## 2. Enable mandatory scope extension for notified bodies

It can be assumed that the official designation procedures will represent a critical bottleneck in the implementation of the AI Act. The sufficient availability of notified bodies, especially at the beginning of implementation, will depend on the relevant designation and notification procedures starting promptly and being completed within a reasonable period of time. Experience shows that the designation process itself takes several months, often even years, because administrative procedures and criteria are often not yet established or are still subject to change at the outset, combined with new requirements for conformity assessment bodies. A streamlined, predictable, and practical accreditation and designation process is therefore a key prerequisite for the successful implementation of the AI Act.

The TÜV Association therefore welcomes the EU Commission's objective of simplifying notification procedures: The proposal adds paragraph 8 to Article 28 of the AI Act, according to which notifying authorities should ensure that conformity assessment bodies can use a single application and a single assessment procedure when they are designated under both the AI Act and a sectoral EU harmonisation act (Annex I.A). Article 29(4) also clarifies that documents and certificates from existing sectoral designations can be used to support accelerated designation under the AI Act.

The proposed adjustments are a step in the right direction, but need to be further specified. Not only is a joint application and a joint assessment procedure required, but it should also be possible to extend existing designations under EU harmonisation law. Conformity assessment bodies that are already designated under sectoral product legislation should be allowed to use their existing designation as a basis for their designation under the AI Act. It should be possible to carry out scope extensions via gap audits. This would significantly speed up the designation process, avoid unnecessary bureaucracy, reduce costs for the economy, and ensure that there are enough qualified notified bodies available when the AI Act enters into force.

### Our recommendations:

- Establish scope extensions with AI-specific proof of competence as the norm for the designation procedure, limit official assessment to gap audits; only provide for full assessments in the case of specifically justified risks
- Obligation to provide justification: National notifying authorities should only be allowed to reject a scope extension on the basis of valid arguments and written justifications

## 3. Delete technology-specific designation codes (AIH codes)

The draft Digital Omnibus introduces a new Annex XIV, which establishes a naming system intended to clarify the scope of designation for conformity assessment bodies. The proposed AIP codes (product-related for Annex I systems) and AIB codes (application-related for biometric systems under Annex III.1) are generally comprehensible and serve to clarify the necessary scope of designation of conformity assessment bodies. However, it is problematic that the proposal also introduces AIH codes as horizontal, technology-related codes to be used in combination with AIP/AIB codes to categorize underlying AI models and technologies even more specifically.

The TÜV Association rejects the introduction of these technology-specific AIH designation codes (such as “symbolic AI”, “machine learning”, “single modality generative AI”, “agentic AI”). This is because they clearly contradict the technology-neutral and application-based approach foreseen in the AI Act: When designating assessment bodies, reliable assessment competencies with regard to areas of application are decisive – not the formal assignment to current AI technologies, which are subject to constant change. Terms such as “agentic AI” or “generative AI” are also dynamic, sometimes vague, and subject to rapid change. This leads to legal uncertainty, as it is not possible to clearly define the required scope of designation of the bodies for assessing specific AI systems, thus unnecessarily expanding the scope of designation.

Particularly in the current, critical ramp-up phase, the introduction of AIH codes threatens to create additional bureaucratic effort without any discernible added value: For most products, several AIH codes are applicable, which makes it more difficult to verify competence, prolongs designation procedures, complicates certification procedures, and thus makes it more expensive for the economy. This counteracts the simplification goals of the Digital Omnibus and increases the risk that there will not be enough notified bodies in place in time.

#### Our recommendations:

- Delete AIH codes in Annex XIV Section 2.3 (a-d) without replacement; designation scopes should primarily be determined by vertical codes (AIP/AIB) and established (technology-neutral) competence and process requirements.
- If a horizontal differentiation is politically imperative, it should not be technology-based, but rather method- or competency-based (e.g. modules for model validation and data governance audit, robustness, cybersecurity interfaces, human oversight audit).
- It must be ensured that the designation system does not become an additional hurdle in the designation process, which would delay the rapid establishment of the assessment infrastructure.

## 4. Simplify technical documentation for SMEs/SMCs with a sense of proportion

The TÜV Association generally supports the approach to ease regulatory requirements not only for SMEs, but also for small mid-cap companies (SMCs). However, it is important to proceed with caution and not to play off the high level of protection provided by the AI Act against reducing bureaucracy. This applies in particular to the extension of the simplified technical documentation from SMEs to SMCs.

The simplified technical documentation for SMEs and SMCs must be designed in such a way that it provides notified bodies and supervisory authorities with all the information necessary for conformity assessment, at least including the elements of Annex IV. Simplifications may only be of a formal and structural nature (e.g. based on standardised templates, modular structure, fewer redundancies), but must not lead to any actual loss of information. To date, the EU Commission has not published a template for a simplified documentation form. In order to provide legal certainty to all parties involved as quickly as possible, the relevant delegated act should be published in a timely manner without substantially reducing the information requirements.

Otherwise, there is a risk that notified bodies will not be able to adequately assess the conformity of the AI system on the basis of the technical documentation. This would mean that additional evidence would have to be requested from the provider, resulting in further iteration loops, time losses, and higher costs for all parties involved.

With a highly simplified technical documentation for SMEs and SMCs, the European legislator runs the risk that non-compliant and unsafe AI-based systems enter the market and endanger users. Therefore, the following principle must continue to apply: The safety of a product must not depend on the size of its manufacturer.

#### Our recommendations:

- Clarification/guidelines: Simplification must be clearly understood as formal simplification; the substantive minimum content specified in Annex IV must not be diluted.
- Ensuring verifiability: The simplified form should be structured in such a way that it fully reflects the evidence required for a robust conformity assessment and makes it efficiently verifiable (checklists/module logic instead of text reduction).
- Rapid, practical provision: The EU Commission should publish the simplified form in a timely manner, involving notified bodies in the process, so that the mandatory acceptance of the form actually leads to relief in practice and does not result in legal uncertainty.

## 5. Ensure legally secure GPAI pre-market conformity assessments

The TÜV Association welcomes the fact that high-risk AI systems derived from powerful general-purpose AI (GPAI) models are also to be subject to mandatory ex-ante conformity assessment. This is consistent, as advanced GPAI models in particular can pose special risks arising from scaling, generalization, and reuse.

However, the legal structure of this requirement in the Digital Omnibus raises more questions than it contributes to legal certainty. The introduction of so-called “pre-market conformity assessments” has now been embedded in Article 75 of the AI Act, now titled “Market surveillance and control of AI systems and mutual assistance.” However, ex-ante conformity assessments and ex-post market surveillance are two completely different systems with different actors and requirements. In addition, the scope of application remains unclear: In the amended paragraph 1, the EU Commission refers to GPAI systems with the exception of product-related AI systems under Annex I, but in the newly added paragraph 1c, it refers to high-risk systems under Article 43, which are subject to third-party verification. Following this logic, only GPAI systems under Annex III, point 1, i.e., biometric systems, would be subject to such a pre-market conformity assessment. Comprehensive legal clarification is needed here.

The TÜV Association takes a rather critical view of the proposal to empower the EU Commission to carry out these pre-market conformity assessments by itself. This approach deviates significantly from the established assessment logic in the New Legislative Framework, which provides for assessments solely by private independent notified bodies, but not by public authorities. A departure from these basic principles of European product legislation entails risks in terms of acceptance, procedure, and capacity, and could weaken confidence in the European quality infrastructure. Although the draft Omnibus

provides for the subcontracting of the assessments to notified bodies, it remains unclear according to which criteria and in which cases such subcontracting will take place, and how exactly certification will be carried out.

When assessing high-risk GPAI systems, the established assessment infrastructure provided by independent notified bodies should therefore be used instead of setting up a parallel assessment infrastructure, provided that sufficient assessment expertise is available. The EU Commission should focus primarily on market surveillance and control of GPAI systems and, in addition, promote the development of specific assessment standards for such systems.

#### Our recommendations:

- Create legal clarity as to which GPAI systems are affected by pre-market conformity assessments
- Prioritize assessment by independent notified bodies, even for high-risk GPAI systems, instead of establishing parallel assessment systems
- Promote the development of specific assessment standards for such systems

## 6. Establish AI regulatory sandboxes at EU level, but not as a substitute for conformity assessments

The TÜV Association welcomes the proposal to establish AI regulatory sandboxes at EU level at the AI Office and to extend real-world testing to Annex I Part B AI systems (e.g. automotive). As protected experimental spaces, regulatory sandboxes can make an important contribution to assessing highly innovative and potentially risky AI systems under realistic conditions, identifying risks at an early stage, and enabling regulatory learning – especially for SMEs and SMCs.

At the same time, a clear distinction must be made: Participation in a regulatory sandbox cannot and must not lead to a presumption of conformity under the AI Act. The TÜV Association emphasizes that conformity assessment procedures always remain mandatory for high-risk AI systems prior to their placing on the market. Regulatory sandboxes serve to test AI systems, not to certify them. Exit reports pursuant to Art. 57(7) of the AI Act may well provide evidence for subsequent conformity assessments, but they do not replace the independent third-party assessment – this expectation must not be raised among stakeholders at all. It is therefore to be welcomed that the EU Commission makes this clear distinction in Article 6(4) of the recently published draft implementing regulation specifying the regulatory sandbox requirements.

The practical design of regulatory sandboxes is key when promoting an implementation that combines innovation and protection goals alike: Regulatory sandboxes should be easily accessible, sector-specific, and equipped with clear guidelines for safety and fundamental rights. At the same time, roles, interfaces, and transitions to conformity assessment should be clearly regulated in order to avoid misguided incentives and legal uncertainty.

Independent conformity assessment bodies can support AI regulatory sandboxes by offering a wide range of services, including general training on compliance challenges, consulting on sandbox-specific requirements, reviewing exit reports for their relevance to subsequent conformity assessment, and

providing testing infrastructure. However, any such involvement must take place within a clear legal framework to rule out any conflicts of interest on the part of conformity assessment bodies (independence, impartiality) with regard to their possible activity as a notified body under the AI Act.

#### Our recommendations:

- Establish a clear differentiation that participation in a regulatory sandbox does not replace subsequent conformity assessment.
- Evidence transfer: Make regulatory sandbox results usable as verifiable inputs. Design exit reports in such a way that they already contain information relevant for conformity assessment.
- Integration of the testing infrastructure: Actively involve independent assessment organisations as important stakeholders in regulatory sandboxes, while establishing a clear legal distinction from notified bodies.

## Further recommendations

### 7. Keep registration requirement for opt-out AI systems

The TÜV Association is critical of the Digital Omnibus's proposal to remove the registration requirement for so-called "opt-out" AI systems. According to the proposal, providers of AI systems used in a high-risk application field as defined in Annex III, but which, according to their own assessment, fall under the exemption in Article 6(3) of the AI Act (e.g. only "narrow or procedural tasks"), would no longer be required to register in the EU database. In the view of the Commission, this would reduce administrative burdens and costs. This being said, the obligation to document the opt-out assessment prior to placing the product on the market and to submit it to national authorities upon request remains in place.

Even though providers are still required to create a documentation, the elimination of the registration requirement removes a necessary transparency and accountability requirement. Opt-out AI systems would no longer be publicly visible or verifiable. Market surveillance authorities, researchers, and civil society actors would thus lose a low-threshold tool for verifying the plausibility and consistency of such self-classifications. This is particularly problematic because opt-out decisions are always made by the provider itself and misjudgements - even unintentional ones - can lead to risk misclassifications. This significantly increases the probability that high-risk AI systems that do not meet the essential requirements of the AI Act will be placed on the market, thereby reducing the level of protection.

Furthermore, the relief effect of such a measure is limited: The essential work (risk analysis, justification, internal approval, and documentation) remains unchanged; the only step that falls away is the registration and upload. In contrast, there is a significant loss of trust and enforceability if opt-out decisions are only visible to AI supervisory authorities on a case-by-case basis "on demand".

#### Our recommendations:

- Retain the registration requirement as a proportionate transparency tool for opt-out decisions (instead of dropping it by deleting Article 49(2)). If this is not politically desirable, ensure that the data is accessible to the authorities. Clarify documentation and decision-making requirements to avoid room for interpretation.

## 8. Promote AI skills development as a safety-critical measure despite its voluntary nature

The TÜV Association takes note of the weakening of the AI literacy provision in the Omnibus proposal. The original obligation for providers and operators of AI systems to implement measures to ensure a sufficient level of AI knowledge and skills (“AI literacy”) as provided for in Article 4 of the AI Act has been converted into a mere recommendation to the EU Commission and the Member States to promote appropriate education and training measures.

This simplification tends to exempt providers and operators of AI systems from AI training measures and shifts responsibility to the EU Commission and member states. Even though this relieves the burden on operators of AI systems in particular, it should be noted that operational and role-specific AI literacy and competence remain an essential prerequisite for the legally compliant application and safe use of high-risk AI systems. Without a minimum level of understanding of how AI works, its risks, and control mechanisms, compliance with other material obligations (e.g. risk management, human oversight) will be difficult to implement in practice. It is therefore important to emphasize that AI users such as companies, NGOs and public authorities are still required to strategically build and promote AI competence internally. This should be done through tailored programmes, tools, and quality-assured support services that comprehensively convey the necessary AI knowledge to employees.

### Our recommendations:

- Promote organisation-based AI literacy and competence strategies through legislation
- Expand specific support programmes/tools at EU and national levels (e.g. service desks, high-quality training courses, including those offered by private education providers, with practical materials)
- Publish EU Commission guidelines and best practices on AI literacy

## Our amendment proposals

Article	Text of the Commission proposal	Amendment proposal	Justification
1(6) 49(2)	<p>in Article 6(4), paragraph 4 is replaced by the following:</p> <p>'4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.';</p>	<p><del>(6) in Article 6(4), paragraph 4 is replaced by the following:</del></p> <p><del>'4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.';</del></p>	<p>The requirement to register "opt-out" AI systems into a public database should be maintained as a necessary transparency and accountability instrument. Opt-out decisions are always made by the provider itself and misjudgements - even unintentional ones - can lead to risk misclassifications. This significantly increases the probability that high-risk AI systems that do not meet the essential requirements of the AI Act will be placed on the market.</p>
1(10)	<p>in Article 28, the following paragraph 8 is added:</p> <p>'8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall be established, organised and operated in such a way that ensures that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section A of Annex I, where the relevant Union harmonisation legislation provides for such single application and single assessment procedure.</p> <p>The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.</p>	<p>in Article 28, the following paragraph 8 is added:</p> <p>'8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall be established, organised and operated in such a way that ensures that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section A of Annex I, <del>where the relevant Union harmonisation legislation provides for such single application and single assessment procedure.</del></p> <p>The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation, <del>provided that the relevant Union harmonisation legislation provides for such a procedure.</del></p>	<p>The proposed adjustments are a step in the right direction, but need to be further specified.</p> <p>Not only is a joint application and a joint assessment procedure required, but it should also be possible to extend existing designations under EU harmonisation law. Conformity assessment bodies that are already designated under sectoral product legislation should be allowed to use their existing designation as a basis for their designation under the AI Act. It should be possible to carry out scope extensions via gap audits.</p> <p>This would significantly speed up the designation process, avoid</p>

	<p>The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation.;</p>	<p>The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation. <b><i>Notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I shall only be required to demonstrate that they meet the requirements laid down in this Regulation.</i></b></p>	<p>unnecessary bureaucracy, reduce costs for the economy, and ensure that there are enough qualified notified bodies available when the AI Act enters into force.</p>
25(c)	<p>(c) the following paragraphs 1a to 1c are inserted: (...)</p> <p>1c. The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply <i>mutatis mutandis</i> to the Commission when exercising its powers under this paragraph.</p>	<p>(c) the following paragraphs 1a to 1c are inserted: (...)</p> <p>1c. The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 <del>that are classified as high-risk and subject to third-party conformity assessment under Article 43</del> before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply <i>mutatis mutandis</i> to the Commission when exercising its powers under this paragraph.</p>	<p>It is welcomed that general-purpose AI (GPAI) models should be subject to mandatory ex-ante conformity assessment. However, the legal structure of this provision raises more questions than it contributes to legal certainty (see detailed explanation above). In order to clearly distinguish between independent assessments of high-risk AI systems by notified bodies (Annex I/III) and pre-market conformity assessments by the EU Commission (GPAI systems), the reference to high-risk AI systems subject to third-party conformity assessments should be deleted.</p>
Annex XIV	<p>Annex XIV</p> <p>The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies</p> <p>1. Introduction Conformity assessment of high-risk AI systems under this Regulation may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories,</p>	<p>Annex XIV</p> <p>The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies</p> <p>1. Introduction Conformity assessment of high-risk AI systems under this Regulation may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories, and corresponding types of AI</p>	<p>The proposed AIP and AIB codes are generally comprehensible and serve to clarify the necessary scope of designation of conformity assessment bodies. However, the introduction of technology-specific AIH designation codes is to be rejected. They clearly contradict the technology-neutral and application-based approach foreseen in the AI Act: When designating assessment bodies, reliable assessment</p>

<p>and corresponding types of AI systems sets the scope of the designation of conformity assessment bodies notified under Article 30 of this Regulation.</p> <p>2. List of Codes, categories, and corresponding AI systems</p> <p>(...)</p> <p><u>3. AI technology-specific codes</u></p> <p><u>a) Symbolic AI, expert systems and mathematical optimization</u></p> <p>AIA Code</p> <p>AIH 0101 Logic- and knowledge-based AI systems that infer from encoded knowledge or symbolic representation, expert systems</p> <p>AIH 0102 Logic-based AI systems, excluding basic data processing</p> <p><u>b) Machine learning, excluding GPAI and single modality generative AI</u></p> <p>AIA Code</p> <p>AIH 0201 AI systems that process structured data</p> <p>AIH 0202 AI systems that process signal and audio data</p> <p>AIH 0203 AI systems that process text data</p> <p>AIH 0204 AI systems that process image and video</p> <p>AIH 0205 AI systems that learn from their environment, excluding agentic AI</p> <p><u>c) AI systems based on GPAI or single modality generative AI</u></p> <p>AIA Code</p> <p>AIH 0301 Single modality generative AI systems</p> <p>AIH 0302 Multimodal generative AI systems, including AI systems based on GPAI models</p> <p><u>d) Agentic AI</u></p> <p>AIA Code</p> <p>AIH 0401 Agentic AI</p>	<p>systems sets the scope of the designation of conformity assessment bodies notified under Article 30 of this Regulation.</p> <p>2. List of Codes, categories, and corresponding AI systems</p> <p>(...)</p> <p><u>3. AI technology-specific codes</u></p> <p><u>a) Symbolic AI, expert systems and mathematical optimization</u></p> <p><del>AIA Code</del></p> <p><del>AIH 0101</del> <del>Logic- and knowledge-based AI systems that infer from encoded knowledge or symbolic representation, expert systems</del></p> <p><del>AIH 0102</del> <del>Logic-based AI systems, excluding basic data processing</del></p> <p><del>— b) Machine learning, excluding GPAI and single modality generative AI</del></p> <p><del>AIA Code</del></p> <p><del>AIH 0201</del> <del>AI systems that process structured data</del></p> <p><del>AIH 0202</del> <del>AI systems that process signal and audio data</del></p> <p><del>AIH 0203</del> <del>AI systems that process text data</del></p> <p><del>AIH 0204</del> <del>AI systems that process image and video</del></p> <p><del>AIH 0205</del> <del>AI systems that learn from their environment, excluding agentic AI</del></p> <p><del>— c) AI systems based on GPAI or single modality generative AI</del></p> <p><del>AIA Code</del></p> <p><del>AIH 0301</del> <del>Single modality generative AI systems</del></p> <p><del>AIH 0302</del> <del>Multimodal generative AI systems, including AI systems based on GPAI models</del></p> <p><del>— d) Agentic AI</del></p> <p><del>AIA Code</del></p> <p><del>AIH 0401</del> <del>Agentic AI</del></p>	<p>competencies with regard to areas of application are decisive - not the formal assignment to current AI technologies, which are subject to constant change.</p> <p>Terms such as “agentic AI” or “generative AI” are also dynamic, sometimes vague, and subject to rapid change. This leads to legal uncertainty, as it is not possible to clearly define the required scope of designation of the bodies for assessing specific AI systems, thus unnecessarily expanding the scope of designation.</p> <p>Particularly in the current, critical ramp-up phase, the introduction of AIH codes threatens to create additional bureaucratic effort without any discernible added value.</p> <p>For most products, several AIH codes are applicable, which makes it more difficult to verify competence, prolongs designation procedures, complicates certification procedures, and thus makes it more expensive for the economy. This counteracts the simplification goals of the Digital Omnibus and increases the risk that there will not be enough notified bodies in place in time.</p>
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## Your contact



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