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EU AI Act

Standard Setting

Establishing harmonised standards for AI systems

July 2025

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Sean Musch, AI & Partners

Michael Borrelli, AI & Partners

Charles Kerrigan, CMS UK

Helen Yu, Tigon Advisory Corp

Mark Butcher, Posetiv Coud Ltd

Andrey Prozorov, ISMS PRO



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AI & Partners defends and extends the digital rights of users at risk around the world. By combining direct technical support, comprehensive policy engagement, global advocacy, grassroots professional services, regulatory interventions, and participating in industry groups such as AI Commons, we fight for fundamental rights in the artificial intelligence age.

This report was prepared by Sean Donald John Musch and Michael Charles Borrelli. For more information visit <https://www.ai-and-partners.com/>.

Contact: Michael Charles Borrelli | Director | m.borrelli@ai-and-partners.com.

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Who Are We

AI That You Can Trust

Why Us?

Stay on the right side of history. At AI & Partners, we believe AI should unlock potential—not cause harm. We've seen the fear and fallout when teams lose control of AI, but also the trust and innovation that follow when it's handled responsibly. That's why we exist: to help you build AI you can trust and stand behind—for the long run.

What Do We Do?

We enable safe AI usage—for your organization and your clients. Unknown AI adoption leads to confusion, risk, and reputational damage. We help you take control with tools to identify, monitor, and govern all AI systems—so you're not reacting to AI, you're leading it.

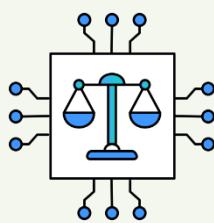
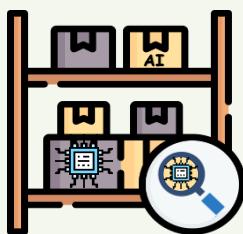
How Do We Do It?

Do you know what AI systems you have? Identify all known and unknown AI systems (algorithms, LLMs, prompts, and models) from all internal and external AI vendors, automated by generating your inventory. Overall, 80% of AI inventory is unknown to our clients.

How do you guarantee ongoing safe AI use? Continuously monitor deployed AI systems for performance drift, anomalies or failures, real-world impacts, and emerging risks (e.g. data poisoning). Any malfunction of an AI system has severe implications for organisations (e.g. inability to assess online misinformation that leads to widespread public mistrust), so monitoring becomes a matter of urgency.

80%

of AI systems
are unknown



AI Discovery & AI Inventory

Automatically detect all AI systems, including models, algorithms, and prompts, and maintain a live, always-updated register for full visibility and compliance.

Responsible AI

Embed fairness, transparency, and control into every stage of AI use—aligning with the EU AI Act and building 'Trustworthy-by-Design'.

Model Monitoring

Continuously track your AI models after deployment to detect drift, bias, or failure—so you stay in control and prevent harm before it happens.



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Introduction

As the EU Artificial Intelligence Act (EU AI Act) continues its implementation path, harmonised standards constitute a key mechanism for supporting safe, transparent, and interoperable AI systems. These consensus-based documents translate legal requirements into practical specifications, helping firms and regulators operationalise the EU AI Act while promoting innovation and trust.

This report serves as a practical blueprint for stakeholders navigating the complex process of standard setting under the EU AI Act. It distils best practices, lessons learned from adjacent domains (such as cybersecurity and digital identity), and actionable insights for fostering coherent, high-quality standards across the EU. From legal alignment and technical documentation to stakeholder engagement and international interoperability, the report identifies opportunities to strengthen Europe's AI ecosystem through effective standardisation.

As a result of mapping out the key roles, responsibilities, and interactions among actors in the standard-setting process—such as the European Commission, European Standardisation Organisations (ESOs), National Standards Bodies (NSBs), Harmonised Standards Consultants, and stakeholder groups—this document promotes a collaborative, transparent, and inclusive approach. It highlights how firms can streamline compliance and market access, how regulators can support public policy objectives, and how end users can benefit from AI systems that are safer, more explainable, and aligned with European values.

Whether you are an SME integrating AI into your products, a regulator preparing for conformity assessment, or a civil society group advocating for ethical AI, this report provides a structured reference for engaging with AI-related standard setting—laying the groundwork for responsible, scalable, and lawful innovation across the EU Single Market.

Best regards,

Sean Musch

Founder/CEO

AI & Partners





Key questions being asked about Standard Setting



1. What is a standard and why is it important?

A standard is a document that provides agreed-upon guidelines, specifications, or criteria to ensure products, services, and systems are safe, reliable, and perform as intended. Standards promote quality, compatibility, and interoperability, helping businesses innovate and compete globally. They also reduce costs by streamlining production and improving consumer confidence. In regulated sectors, complying with standards often demonstrates adherence to legal requirements. By aligning technical practices across borders, standards also facilitate international trade and support public policy objectives like safety, health, environmental protection, and digital transformation.

2. Who develops standards in Europe?

In Europe, standards are primarily developed by recognised European Standardisation Organisations (ESOs) such as CEN, CENELEC, and ETSI. These organisations collaborate with National Standards Bodies (NSBs) from EU and EFTA countries. NSBs nominate experts to participate in technical committees, which draft standards based on consensus. Stakeholders include industry representatives, regulators, consumer organisations, and academia. The process is inclusive, transparent, and consensus-driven, ensuring balanced representation. Once developed and approved, standards can be adopted at national level and, if harmonised, can offer presumption of conformity with EU legislation when published in the Official Journal of the European Union.

3. What is a harmonised standard?

A harmonised standard is a European standard developed by an ESO under a formal request (mandate) from the European Commission to support EU legislation. Once assessed for compliance and published in the Official Journal of the European Union (OJEU), it provides a "presumption of conformity" with relevant legal requirements, such as safety, health, or environmental protections. Manufacturers can use harmonised standards to demonstrate compliance, simplifying CE marking and market access. Though voluntary, these standards are widely used due to their legal benefits and efficiency in proving conformity with applicable EU directives and regulations.

4. How are stakeholders involved in the standard-setting process?

Stakeholders play a central role throughout the standard-setting process. Technical committees formed by standardisation bodies include representatives from industry, public authorities, NGOs, academia, and consumer groups. During the Enquiry stage, draft standards are publicly circulated for comment, enabling broad participation. Feedback helps ensure standards are practical, relevant, and widely accepted. This inclusive approach enhances legitimacy and transparency. At national level, NSBs also consult stakeholders to form national positions during European voting. This collaboration ensures diverse needs are reflected, helping to build consensus and create balanced, technically sound, and widely applicable standards.

5. What is the role of the European Commission in standardisation?

The European Commission plays a strategic and regulatory role in the European standardisation system. It issues standardisation requests (mandates) to ESOs for developing harmonised standards that support EU legislation. The Commission also monitors implementation, provides funding for standardisation activities, and ensures legal coherence. After development, it assesses whether the standard meets the legal requirements before publishing it in the OJEU. Through this, the Commission ensures that standards serve public policy goals, such as safety, innovation, sustainability, and digitalisation. It also promotes inclusiveness and ensures alignment with international and internal market regulations.



6. What is the Enquiry stage in standard development?

The Enquiry stage is a formal public consultation phase where draft standards are circulated to stakeholders for review and comment. Managed by National Standards Bodies (NSBs), this stage typically lasts 60 to 90 days. It allows industry, consumers, regulators, and other interested parties to submit feedback on the draft's content, clarity, and applicability. All comments are reviewed by the responsible technical committee, and revisions may be made based on stakeholder input. This stage ensures transparency, fosters consensus, and improves the quality and relevance of the final standard before it advances to the approval phase.

7. What happens after a harmonised standard is approved?

Once approved and assessed for compliance, the harmonised standard is published in the Official Journal of the European Union (OJEU). This publication grants it legal status and allows manufacturers to use it to demonstrate compliance with EU directives or regulations. National Standards Bodies then adopt it into their national catalogues, withdrawing any conflicting national standards. From this point, products or services complying with the standard are presumed to meet the applicable legal requirements, simplifying regulatory approval and market access across the EU. This step ensures uniformity and strengthens the Single Market.

8. Are standards legally binding?

Standards are generally voluntary unless referenced in legislation or made mandatory by contractual or regulatory requirements. Harmonised standards, while not legally binding on their own, offer a presumption of conformity with specific EU laws when listed in the Official Journal of the European Union. This means that compliance with the standard is one way—but not the only way—to meet legal obligations. Manufacturers may choose alternative methods, but they must then provide evidence of compliance. In practice, most companies adopt standards to benefit from legal certainty, cost efficiency, and smoother access to European and global markets.

9. Can standards be revised or withdrawn?

Yes, standards are reviewed periodically—typically every five years—to ensure they remain up to date and relevant. Based on this review, they may be confirmed, revised, or withdrawn. Revisions are often prompted by technological advancements, market evolution, or changes in legal requirements. Stakeholders can also propose updates if issues arise. The revision process follows the same consensus-based approach, with public consultation and technical evaluation. Withdrawal occurs when a standard is outdated, replaced, or no longer needed. National Standards Bodies reflect these changes in their catalogues, maintaining alignment with European and international standardisation practices.

10. How do standards support innovation and competitiveness?

Standards provide a stable framework for innovation by defining clear technical requirements, interoperability criteria, and safety benchmarks. They reduce uncertainty for developers and investors, enabling faster product development and market entry. By facilitating compatibility and system integration, standards open new markets and encourage collaboration across industries. For small and medium enterprises (SMEs), they level the playing field, ensuring access to best practices and helping meet regulatory demands. Moreover, standards foster global competitiveness by aligning European products with international expectations, enhancing quality, and supporting sustainable growth. They are essential tools in scaling innovation while maintaining trust and compliance.

Understanding Standard Setting





1. Creation of Standardisation Request



What happens here?

Why is this necessary?

How is this actioned?

The European Commission prepares a formal standardisation request, also known as a mandate, in collaboration with European Standardisation Organisations (ESOs) and key stakeholders. This document outlines the purpose, legal framework, technical scope, policy objectives, and timelines for developing a standard. Once drafted, it is reviewed by the Committee on Standards, made up of Member State representatives, before formal adoption. The request is then published in the EU's official communication channels. This step officially launches the process and empowers the ESOs to begin technical work on the requested standard.

The standardisation request ensures that European standards are aligned with legislative needs and policy objectives established by the EU. It acts as a contract between the Commission and the ESOs, giving clear legal authority and defining expected outcomes. Without this structured foundation, there would be a risk of misalignment between standards and EU laws, such as safety directives or product regulations. This clarity is essential for granting harmonised standards the legal status that gives products "presumption of conformity" with relevant EU requirements, ensuring uniform compliance across all Member States.

The European Commission develops the draft request internally, often with input from subject matter experts, ESOs, Member States, and other stakeholders. Once the draft is ready, it is reviewed by the Committee on Standards, representing EU Member States. After receiving majority support, the request is officially adopted and published. This formal act triggers the start of the standardisation process. The European Commission may also coordinate with stakeholders to ensure that the request is technically and economically feasible. Once adopted, ESOs are responsible for initiating the drafting phase according to the request's terms.



2. Drafting of Standards



What happens here?

Why is this necessary?

How is this actioned?

European Standardisation Organisations (ESOs)—such as CEN, CENELEC, or ETSI—begin the technical work to create the standard. They establish technical committees or working groups composed of experts nominated by National Standards Bodies (NSBs), industry, and relevant stakeholders. These experts draft the standard based on consensus, often referencing existing international standards (e.g., ISO, IEC) for alignment. The drafting process involves detailed technical discussions, iterative revisions, and internal reviews. The result is a well-structured draft standard that aims to meet the legal and technical requirements outlined in the original standardisation request issued by the European Commission.

The drafting stage transforms high-level policy goals into concrete, practical technical documents. It's necessary because legislation alone can't specify every detail for safe, interoperable, and compliant products or services. This stage ensures that the technical content of standards is informed by a wide range of expertise and practical knowledge. Involving diverse actors—industry, public bodies, consumer groups—helps ensure that the standards are usable, up-to-date, and broadly supported. The consensus approach strengthens market relevance and reduces the likelihood of disputes or resistance once the standard is adopted and implemented across EU Member States.

Once the standardisation request is published, the responsible ESO assigns the task to the appropriate technical committee. The committee includes delegates from national bodies, stakeholders, and technical experts. Drafting follows established rules to ensure transparency, inclusiveness, and consensus. ESO secretariats coordinate the process, maintain documentation, and ensure deadlines are met. Drafts are circulated internally for comments and continuously refined. International standards may be incorporated to maintain global compatibility. Once the committee agrees on a version suitable for wider consultation, the draft proceeds to the next stage—public enquiry—where additional feedback is collected from national stakeholders.



3. Enquiry



What happens here?

Why is this necessary?

How is this actioned?

During the Enquiry stage, National Standardisation Bodies (NSBs) solicit and collect feedback from stakeholders—including industry experts, regulatory bodies, consumer groups, and the public—on a draft version of the proposed standard. This open consultation process is formal and typically time-bound, allowing a diverse range of opinions to be submitted. Comments may concern technical content, applicability, or clarity. After the consultation period ends, all feedback is reviewed by relevant committees or working groups. Based on this input, the draft may be revised before it progresses further. This stage ensures comprehensive scrutiny and transparency in standard development.

"The Enquiry stage is crucial because it ensures that the draft standard is examined through a wide lens, capturing the insights, concerns, and expectations of all affected parties. By engaging stakeholders early, it helps identify potential issues, enhances clarity, and increases practical applicability across different sectors. This collaborative approach builds trust, promotes buy-in, and helps prevent the release of flawed or biased standards. Furthermore, it aligns the standard with market needs, legal frameworks, and technological developments, making it more robust and widely accepted. Ultimately, this process improves the quality, legitimacy, and relevance of the final standard."

The Enquiry stage is implemented through a structured, transparent public consultation process. NSBs publish the draft standard on official platforms and invite comments from stakeholders within a defined timeframe—usually 60 to 90 days. Notifications may be sent through email, newsletters, or industry publications to encourage participation. Respondents submit feedback via standardized forms or online portals. After the consultation closes, technical committees systematically review all submissions. Accepted changes are incorporated into the revised draft, with justifications often provided for accepted or rejected comments. This version may then proceed to the approval stage, depending on consensus and review outcomes.



4. Harmonised Standards Consultants



What happens here?

Why is this necessary?

How is this actioned?

At this stage, independent Harmonised Standards Consultants (HSCs) conduct a detailed assessment of the draft standard to ensure it aligns with the requirements set out in the original standardisation request issued by the European Commission. Their review focuses on legal compliance, coherence with EU legislation, and the appropriate integration of essential requirements. This assessment occurs before the formal voting stage. If the draft meets the necessary criteria, the consultants give their approval. Only editorial or minor technical changes are permitted afterward, preserving the legal integrity of the text as it advances toward formal adoption.

This step is necessary to guarantee that the draft standard fulfills the legal and policy expectations of the European Commission. Harmonised standards often serve as a presumption of conformity with EU legislation, so they must accurately reflect relevant legal requirements. By involving independent consultants, the process gains objectivity and legal rigor. This step prevents the adoption of standards that could misalign with EU directives or fail to ensure safety, health, or environmental protections. Early validation avoids legal conflicts, ensures smoother regulatory acceptance, and reinforces the credibility and enforceability of the final harmonised standard.

Harmonised Standards Consultants are engaged by the European Commission or relevant standardisation bodies. Once the draft standard is ready, it is submitted to these consultants for a compliance assessment. The consultants evaluate whether the draft aligns with the standardisation request and EU legal requirements, including references to directives or regulations. Their review is formal, often involving documented comments and required revisions. The standard must receive a positive opinion before proceeding to a formal vote by National Standardisation Bodies. If needed, adjustments are made to the draft based on the consultants' input, but post-vote changes are limited to maintain legal coherence.



5. Inclusion in OJEU



What happens here?

Why is this necessary?

How is this actioned?

At this stage, the standard—after passing all necessary assessments and approvals—is officially published in the Official Journal of the European Union (OJEU). This act marks its formal recognition as a harmonised standard. Once listed, the standard carries legal weight by providing a “presumption of conformity” with the relevant EU legislation, such as directives or regulations. This means that products, services, or processes that comply with the standard are presumed to meet essential legal requirements, simplifying compliance and market access. This publication is the final step in the harmonisation process and solidifies the standard’s legal and regulatory significance within the EU.

Inclusion in the OJEU is essential because it transforms a voluntary technical standard into a legally recognised harmonised standard. This status enables economic operators to demonstrate compliance with EU legal requirements more easily. It reduces administrative burdens, enhances legal certainty, and facilitates the free movement of goods across the internal market. The publication ensures transparency, allowing regulators, manufacturers, and market surveillance authorities to clearly identify which standards confer legal conformity. Without this step, a standard—even if technically sound—would not hold official legal standing in the EU system, limiting its practical utility in demonstrating compliance with relevant legislation.

Once a standard has been reviewed and approved—typically by Harmonised Standards Consultants and relevant standardisation bodies—it is submitted to the European Commission for formal listing. The Commission, after confirming compliance, arranges for its inclusion in the Official Journal of the European Union. This listing includes the reference number of the standard, its title, and the legislation it supports. The update is published as part of a consolidated list of harmonised standards, accessible to the public. From this point forward, conformity with the listed standard provides a presumption of compliance with EU law, benefiting manufacturers, regulators, and consumers alike.



6. Adoption by NSBs



What happens here?

Why is this necessary?

How is this actioned?

Once a standard is published in the Official Journal of the European Union (OJEU) as a harmonised standard, National Standards Bodies (NSBs) across EU member states adopt it into their national standards catalogues. This means the European standard is given a national designation and made available in each country's official system. In addition to adoption, NSBs are required to identify and withdraw or revise any existing national standards that conflict with the newly harmonised version. This process ensures consistency, prevents duplication or contradiction, and supports unified implementation of technical regulations across the European Single Market.

This step is necessary to ensure harmonisation and legal coherence across all EU member states. By adopting the harmonised standard nationally and removing conflicting national standards, NSBs help eliminate technical barriers to trade within the Single Market. This fosters uniform application of safety, environmental, and performance requirements across industries, making compliance easier for manufacturers operating across borders. It also upholds the principle of mutual recognition and supports legal certainty. Without this step, conflicting national standards could undermine the harmonised approach, create confusion for businesses, and compromise the effectiveness of EU legislation and standardisation efforts.

Following publication in the OJEU, the European standard is circulated to all NSBs, who are obligated to adopt it identically as a national standard—usually by translating the title and assigning a national reference code. The content must remain unchanged. Simultaneously, NSBs review their existing catalogues to identify any conflicting national standards, which are then withdrawn or aligned with the harmonised version. This process is tracked and reported to the relevant European standardisation organisations (e.g., CEN or CENELEC) to ensure compliance. The adopted standard is then promoted to stakeholders, making it the recognized benchmark at national level.



Mapping Standard Setting to Ecosystem Actors





Executive body of the EU, proposing legislation, enforcing laws, and coordinating policies including standardisation across member states.



European Standards Organisations

Official EU-recognised bodies (CEN, CENELEC, ETSI) responsible for developing and maintaining harmonised European standards for goods and services.



National Standards Bodies

National entities representing member states in ESOs, coordinating the development, adoption, and implementation of standards domestically and internationally.



European Stakeholder Organisations

EU-recognised groups representing industry, consumers, or societal interests in standardisation processes, ensuring inclusiveness and broad stakeholder participation.



Harmonised Standards Consultants

Experts appointed by the European Commission to assess draft standards for compliance with EU legislation before citation in the Official Journal.



Standard Setting		Actor(s)				
Section	Description	European Commission	European Standards Organisations	National Standards Bodies	European Stakeholder Organisations	Harmonised Standards Consultants
Creation of Standardisation Request	The European Commission drafts a standardisation request detailing the scope, legal requirements, and timelines, in consultation with ESOs and stakeholders. Once approved, the request is published, initiating the formal process for the European Standardisation Organisations (ESOs) to develop the corresponding technical standards.	The European Commission initiates the standardisation process by drafting the standardisation request (also called a "mandate"). This document defines the scope, legal basis, policy objectives, and deadlines for the proposed standard(s). The Commission consults European Standardisation Organisations (ESOs) and stakeholders to ensure alignment with EU legislative needs. Once finalised and approved by the Standardisation Committee (composed of Member State representatives), the request is published, formally starting the process. This stage illustrates the Commission's strategic role in steering the direction of harmonised standards toward policy priorities, such as safety, sustainability, or digital	Although the European Commission leads the drafting of the standardisation request, ESOs—primarily CEN, CENELEC, and ETSI—are closely involved through consultation. Their input helps define technical feasibility, existing work, and necessary resources. This collaboration ensures the request aligns with both EU policy goals and practical standardisation capacities. ESOs may advise on scope or timeline adjustments before formal approval.	Although NSBs don't lead this stage, they are indirectly involved through their participation in ESO governance. When the Commission drafts a standardisation request, NSBs may provide preliminary feedback via their representation in CEN, CENELEC, or ETSI structures. This ensures early input on national interests, technical capacity, and policy alignment.	European Stakeholder Organisations—such as ANEC (consumers), ECOS (environment), ETUC (trade unions), and others—are often consulted by the European Commission during the preparation of a standardisation request. Their involvement helps ensure that societal interests are considered from the outset, particularly when standards relate to consumer safety, accessibility, sustainability, or worker protection. These organisations may participate in advisory forums or targeted stakeholder consultations, shaping the scope and priorities of the request.	Harmonised Standards Consultants are not involved in the initial drafting of the standardisation request. However, their future role is indirectly shaped by the legal clarity and specificity of the request, which sets the criteria against which they will later assess the standard. The more precise the Commission's mandate, the more straightforward their evaluation process will be.



		transformation .				
Drafting of Standards	ESOs coordinate the drafting via a joint technical committee (e.g., CEN-CENELEC), which includes experts from National Standards Bodies (NSBs) and observers. A working group drafts the standard based on consensus, often referencing existing ISO or IEC standards to align with international trade obligations.	Although the ESOs are responsible for coordinating the drafting of technical standards, the Commission maintains oversight. It may attend working group or technical committee meetings as an observer, particularly when the standard supports key legal frameworks like the General Product Safety Regulation or the Machinery Directive. Its role here ensures that EU policy objectives remain embedded in technical content, even though it does not contribute directly to the drafting itself.	This is the core operational stage for ESOs. Once the request is accepted, the relevant ESO (or a joint effort like CEN-CENELEC) forms a technical committee or working group comprising national delegates and technical experts. The working group drafts the standard through consensus, often building upon existing international standards (e.g. ISO or IEC) to ensure global compatibility. ESOs provide the technical infrastructure and secretariat functions necessary for coordination, documentation, and progress monitoring.	NSBs play a vital operational role here. They nominate national experts to the relevant technical committees or working groups established by ESOs. These experts contribute directly to the drafting process. NSBs also serve as liaisons, coordinating national positions and relaying technical or political concerns to the European level. Their participation is essential for ensuring that national perspectives are embedded in the standard while building pan-European consensus.	During the drafting phase, European Stakeholder Organisations can participate in ESO technical committees or working groups as observers or expert members. Although they often do not have voting rights, their role is crucial in introducing societal perspectives and defending non-commercial interests. Their technical contributions may focus on inclusiveness, safety, environmental sustainability, or ethical concerns. This participation ensures that the draft standard serves broader public interests alongside industry goals.	Consultants are not active during the drafting phase, but their later assessment influences how technical committees frame their work. Drafting groups are aware that their work will be scrutinised for legal alignment, so they may preemptively structure content to facilitate the consultant review, particularly on essential requirements like safety, health, or environmental protection.
Enquiry	NSBs gather stakeholder feedback on the draft standard. This public consultation may lead to revisions, ensuring that the final draft reflects broad input and enhances the	During the enquiry stage, the Commission monitors the public consultation process coordinated by National Standards Bodies (NSBs). While it does not manage	ESOs manage the formal enquiry stage by distributing the draft standard to all National Standards Bodies (NSBs) for public consultation. They consolidate feedback and	NSBs are responsible for organizing the public enquiry (national consultation) within their respective countries. They disseminate the draft to stakeholders	Stakeholder Organisations actively engage during the public enquiry phase by reviewing the draft standard and submitting comments, either directly or via National Standards	The public consultation phase remains outside the consultants' scope. However, the outcomes from stakeholder feedback might lead to revisions that





	standard's relevance, acceptance, and quality before advancing in the harmonisation process.	feedback directly, it pays close attention to any stakeholder concerns that might affect the standard's legal or policy relevance. This stage allows the Commission to informally influence revisions and safeguard alignment with EU interests.	ensure revisions reflect broad stakeholder input. This process reinforces the legitimacy and market relevance of the standard.	—such as industry, academia, public authorities, and civil society—and collect feedback. NSBs then consolidate this feedback and submit a national position to the ESO. This stage ensures democratic legitimacy and technical quality of the standard through inclusive dialogue.	Bodies. Many operate Europe-wide and also encourage their national members to participate in national consultations. Their feedback often highlights overlooked issues or proposes alternative wording to improve accessibility, fairness, or environmental impact.	affect legal compliance—ultimately relevant to the consultants' later evaluation.
Harmonised Standards Consultants	Independent consultants assess whether the draft standard meets the requirements of the original standardisation request. Their approval is essential before the vote, ensuring legal compliance. Only minor changes are allowed post-vote to maintain integrity and coherence with the Commission's mandate.	The Commission appoints independent Harmonised Standards Consultants to evaluate whether the draft meets the original request's requirements. This ensures legal consistency with EU law and protects the presumption of conformity granted in later stages.	ESOs are responsible for submitting the draft standard to Harmonised Standards Consultants for legal and technical evaluation. While the consultants are independent, ESOs must support the process by providing documentation or clarifications required by Harmonised Standards Consultants during the compliance review.	NSBs are not directly involved in the legal assessment, but they may assist ESOs in providing documentation or clarifications required by Harmonised Standards Consultants during the compliance review.	Stakeholders typically have no formal role in this legal compliance stage but may raise concerns if they believe a draft standard does not meet legal or societal expectations.	This is the critical stage for Harmonised Standards Consultants. Contracted by the European Commission, these independent experts evaluate whether the draft standard meets the legal and policy requirements set out in the standardisation request. They focus on clarity, legal coherence, and coverage of essential requirements under relevant EU legislation (e.g., safety directives). Only minor, editorial revisions are permitted





						after their positive opinion—ensuring that what's voted on reflects their reviewed version.
Inclusion in OJEU	Once deemed compliant, the standard is published in the Official Journal of the European Union (OJEU). This formal publication grants it the status of a “harmonised standard,” offering a presumption of conformity with relevant EU legal requirement.	Upon successful assessment, the Commission authorises publication of the harmonised standard in the Official Journal of the EU (OJEU), granting it legal effect. It also monitors NSB adoption to ensure Member States uphold the Single Market's legal coherence.	After approval, ESOs formally submit the final version of the standard to the European Commission, requesting its citation in the Official Journal of the EU (OJEU).	NSBs are notified once the standard is published in the Official Journal of the EU (OJEU), marking its harmonised status.	Stakeholder Organisations may issue responses or policy briefs once a standard is published in the OJEU, particularly if it impacts public health, safety, or rights.	Only if consultants approve the standard can it be cited in the Official Journal of the European Union (OJEU), granting it harmonised status and a presumption of conformity.
Adoption by NSBs	National Standards Bodies adopt the new harmonised standard into their national catalogues. They must also remove or revise any conflicting national standards to ensure legal coherence and alignment across the EU Single Market.	Upon successful assessment, the Commission authorises publication of the harmonised standard in the Official Journal of the EU (OJEU), granting it legal effect. It also monitors NSB adoption to ensure Member States uphold the Single Market's legal coherence.	ESOs oversee the uniform adoption of the standard across Member States by coordinating with NSBs to ensure withdrawal of conflicting national standards.	NSBs are responsible for formally adopting the harmonised standard into their national catalogue. They must also withdraw or revise any conflicting national standards, ensuring alignment across the EU Single Market.	They often work with national bodies to promote awareness and uptake of the new harmonised standard, while ensuring it's implemented in a way that reflects the public interest.	After OJEU publication, consultants' involvement concludes. They play no role in national adoption processes.



Calls to Action





Track and Participate in Standardisation Consultations

Enterprises should monitor European Commission initiatives and engage in consultations during the creation of standardisation requests. Early involvement ensures business needs are considered and prepares companies for upcoming technical and regulatory changes.



Submit Formal Feedback During Public Consultations

Enterprises must actively review draft standards during the enquiry phase and provide structured feedback through their NSBs. This participation ensures that practical concerns are addressed and that final standards are fit-for-purpose.



Pre-Assess Draft Standards Against Legal Requirements

Enterprises should internally review draft standards against the original standardisation request criteria to anticipate consultant evaluations. This proactive approach ensures early identification of potential compliance challenges and informs corporate advocacy where necessary.



Update Compliance Systems Upon OJEU Publication

Upon a standard's publication in the Official Journal, enterprises must immediately integrate it into their compliance and product design processes. Harmonised standards grant presumption of conformity, so timely updates minimize legal and market access risks.





Conclusion

The introduction of harmonised standards under the EU AI Act represents a transformative shift in how AI systems are designed, assessed, and deployed—moving toward a more consistent, transparent, and legally robust compliance model. By providing clear technical specifications and shared benchmarks, harmonised standards help translate the AI Act’s legal obligations into practical implementation pathways, reducing uncertainty for innovators while supporting regulatory oversight and safeguarding fundamental rights.

Throughout this report, we have highlighted how the standard-setting process serves as a critical convergence point for AI firms, regulators, and stakeholders—facilitating inclusive dialogue, technical consensus, and market-wide interoperability. When thoughtfully developed, harmonised standards can accelerate alignment with the AI Act’s requirements for data governance, human oversight, transparency, and lifecycle risk management, while fostering trust and innovation across the EU Single Market.

However, successful adoption of harmonised standards depends on more than robust technical drafting—it requires operational readiness, proactive participation, and continual alignment with evolving legal and societal expectations. Stakeholders must adapt compliance systems, product development processes, and governance models to reflect these new standards. Smaller companies and first-time participants may encounter challenges, making early engagement with standardisation bodies and collaborative advocacy essential.

Despite these complexities, forward-leaning organisations, regulators, and civil society actors are already demonstrating that harmonised standards can streamline compliance, drive product quality, and enhance market confidence. As AI systems become more deeply embedded across sectors—from manufacturing and mobility to healthcare and financial services—harmonised standards provide a powerful tool for ensuring that innovation in AI remains not only technically sound and competitive, but also lawful, ethical, and aligned with European values.





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