A European standardisation system fit for global influence

Executive summary

The European standardisation system is a successful example of a public–private partnership where roles are clearly defined, and technical expertise drives outcomes. The separation between legislative and standardisation processes has allowed industry-led standards development to keep pace with innovation, whilst safeguarding the single market's core objective: the free movement of goods.

The Standardisation Regulation has proven effective in supporting harmonised standards across Europe.[1] These standards have facilitated faster market access, reduced compliance costs and ensured legal certainty for businesses across the European Economic Area.

Whilst there is merit in reviewing how the system operates, the real challenges lie not in the legal framework itself but in how it is implemented. This paper identifies concrete, practical reforms that should guide the upcoming review, focused on concrete operational fixes.

Key priorities include:

▶▶ **Improving strategic coordination**, particularly by using existing structures such as the Multi-Stakeholder Platform (MSP) and the High-Level Forum;

▶▶ **Addressing delays in the citation of harmonised standards and reducing divergence from international norms**. Reforms should include a clearer, faster process for assessing standards, more effective reuse of international specifications and a modular approach to standard-setting that aligns with digital innovation cycles; and

▶▶ **Establishing a sustainable funding mechanism** to support the publication and public availability of harmonised standards, whilst fairly compensating copyright holders.

Above all, the EU must resist the urge to redesign what already works. A new agency would add complexity without solving the real problems. What's needed is a renewed commitment to coordination, clarity and

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[1] Regulation (EU) No 1025/2012. This paper builds on our July 2024 position, *Assessing merits and bottlenecks in Europe's standardisation system*, available at https://cdn.digitaleurope.org/uploads/2024/07/DIGITALEUROPE_Assessing-merits-and-bottlenecks-in-Europes-standardisation-system_.pdf.

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implementation, allowing Europe's standardisation system to continue delivering trusted, globally relevant standards.

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Strengthening the public–private partnership

The success of Europe's standardisation system depends on leveraging the experience and expertise of industries developing digital products and services. This public–private partnership is essential for defining global standards that enhance Europe's sustainability and competitiveness globally.

The Competitiveness Compass proposes a revision of the Standardisation Regulation.[2] Whilst we support its overarching goals – speeding up standardisation and citation, strengthening industry engagement and reinforcing Europe's global role – we see **no need for a full revision** of the Regulation's core provisions. These already support a future-proof framework for delivering standards that underpin a resilient single market.

The real challenges lie in implementation, not legislation. A comprehensive overhaul will divert attention from the urgent operational changes needed to boost Europe's competitiveness and innovation.

Improving strategic coordination

As standardisation becomes more geopolitical – influencing trade, digital sovereignty and industrial competitiveness – the EU must coordinate its priorities effectively. Today, responsibilities for the European standardisation system are fragmented across directorates-general (DGs): DG GROW holds the central role, whilst DGs CONNECT and TRADE address the ICT and global dimensions, and other DGs contribute in different legislative contexts. **Improved cross-DG coordination** is essential to reduce siloed approaches.

Recent discussions about establishing a 'European Standardisation Agency' reflect concerns about fragmentation. However, **rather than creating new institutions, the EU should fully resource and empower its existing platforms**.

Europe already has collaborative structures designed to ensure strategic alignment and broad stakeholder input — notably the High-Level Forum on European Standardisation and the Multi-Stakeholder Platform (MSP) on ICT Standardisation. The MSP plays a uniquely valuable role by bringing together EU institutions, Member States, European standardisation organisations (ESOs), civil society, and global standards development organisations (SDOs), making it a key vehicle for strengthening Europe's standardisation system.

Assessing bottlenecks in current implementation

A **dedicated task force** to examine bottlenecks in the standardisation process is a necessary and timely step. The main challenges do not lie in the Regulation itself, but in how its implementation has evolved over the years.

Citation delays remain one of the most pressing issues. The changes introduced after the James Elliott court case, combined with new requirements in the Vademecum, have caused significant delays and uncertainty in the citation of harmonised standards.[3] The Commission's prescriptive approach, including

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[2] COM(2025) 30 final.

[3] C-613/14 and SWD(2015) 205 final, respectively.

detailed work programmes and rigid timelines, puts undue pressure on technical experts and compromises the quality of standards.

These challenges are compounded by a **growing divergence from international standards**. European adaptations of global norms often require additional specifications, increasing development time, costs and technical barriers to trade. This undermines alignment with global supply chains, especially in ICT, and weakens Europe's international competitiveness.

Confusion amongst economic operators is also growing. Lists of harmonised standards are frequently outdated or incomplete, creating legal uncertainty for manufacturers, importers, customs authorities and market surveillance bodies. SMEs are of course particularly affected. This degrades the CE marking's reliability and hinders implementation of EU policy goals.

To address these issues, the EU needs a **renewed commitment to coherence with international standards**. Most regulatory needs, even in emergent areas like AI or cybersecurity, can be met using existing international standards.[4] These should be **fully adopted** to reduce duplication and leverage global expertise.

Given the layered nature of digital technologies, standards development should follow a **modular approach**, allowing partial standards to be used for compliance as they are developed. This would accelerate the availability of usable standards and support faster alignment with global efforts, particularly where international initiatives are already advancing.[5]

Finally, a clear process for **fast-tracking the adoption of external standards**, from recognised SDOs and global consortia, is needed. This would reduce delays and increase flexibility.

Simplifying processes and incentivising stakeholder participation

Europe's standardisation system has succeeded in bringing together a broad range of stakeholders to develop inclusive high-quality standards. Unlike many jurisdictions, Europe benefits from a model that fosters openness, technical excellence and public–private consensus.

This strength should be built upon. Simplifying processes and creating the right incentives can make participation even more effective – particularly for SMEs, researchers and societal stakeholders – and ensure that Europe continues to lead by example.

Inclusiveness

The Regulation enables broad stakeholder participation – from large companies to SMEs, from civil society to public bodies – ensuring that standards reflect diverse interests and expertise. Final approval by national standardisation bodies (NSBs) confirms that these specifications are developed through consensus and reflect the state of the art.

There is, however, significant **potential to increase participation by SMEs and researchers**. As highlighted in recent work by the HLF and the MSP Task Force on R&I and standardisation, financial support alone is not enough. What's needed is an ecosystem that combines **targeted funding, skills development**

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[4] These include ISO, IEC, ITU, W3C, IEEE and OCI.

[5] The Digital Product Passport is a prime example. Whilst CEN-CENELEC JTC24 is actively developing harmonised standards, parallel efforts are already underway in ISO.

and structured linkages between research and industry (e.g. through Erasmus-style exchange programmes). This would empower innovators and users alike to engage meaningfully in standardisation.

To ensure accountability, funding instruments such as StandICT, CyberStand and BlockStand should be reviewed to strengthen their connection to measurable contributions, helping focus support where it can have the greatest impact.

Openness and alternative processes

Europe has long embraced a default-to-international approach in standardisation, reflected in instruments like the Frankfurt and Vienna agreements.[6] This approach should be further opened to **include high-quality standards and specifications developed by recognised international fora and consortia**, provided they meet essential requirements and uphold core WTO principles.[7]

The Regulation's Arts 13 and 14 entrust the MSP with identifying technical specifications to support legislation, particularly in the context of public procurement. However, this role is expanding without adequate safeguards to ensure alignment with market practices – it should **not result in *de facto* mandatory specifications that do not reflect industry consensus and narrow technological choice**.[8]

A more transparent process is needed to allow legitimate global specifications to support compliance. This avoids duplication of effort and accelerates implementation. ESOs should lead this work, drawing on existing procedures such as the ETSI publicly available specifications (PAS) process, with guidance and input from MSP members.

Speed and quality of standards

Faster development of harmonised standards is a valid objective, but comparisons with other jurisdictions must take context into account. Non-market economies may deliver faster outcomes, but often lack the safeguards Europe rightly values: consensus, inclusiveness and transparency. These principles underpin the legitimacy and technical quality of European standards.

Timelines vary significantly depending on the maturity of the technology. Whilst established domains like electromagnetic compatibility (EMC) require less time, **emerging areas such as AI or cybersecurity need broader consultation and consensus-building**. Harmonised standards demand extra care due to their legal implications.

One of the main bottlenecks is the low rate of positive assessments by HAS consultants. **Until mid-2022, only around 19 per cent of submitted standards received a positive evaluation**. Even when the Commission overrides these assessments, as in the case of the RED delegated act on cybersecurity,[9] the delays cause considerable uncertainty and frustration for experts and industry. Companies are increasingly

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[6] Agreement on technical cooperation between ISO and CEN ('Vienna agreement') and IEC-CENELEC agreement on common planning of new work and parallel voting ('Frankfurt agreement').

[7] These include W3C, IETF, IEEE, OASIS and OCI.

[8] For instance, in implementation of the Data Act (Regulation (EU) 2023/2854).

[9] Commission Delegated Regulation (EU) 2022/30, as amended by Commission Delegated Regulation (EU) 2023/2444.

questioning whether the time and resources they invest in standardisation are justified when harmonised standards are not cited in a timely manner.

Outcome of assessment reports per sector since August 2022
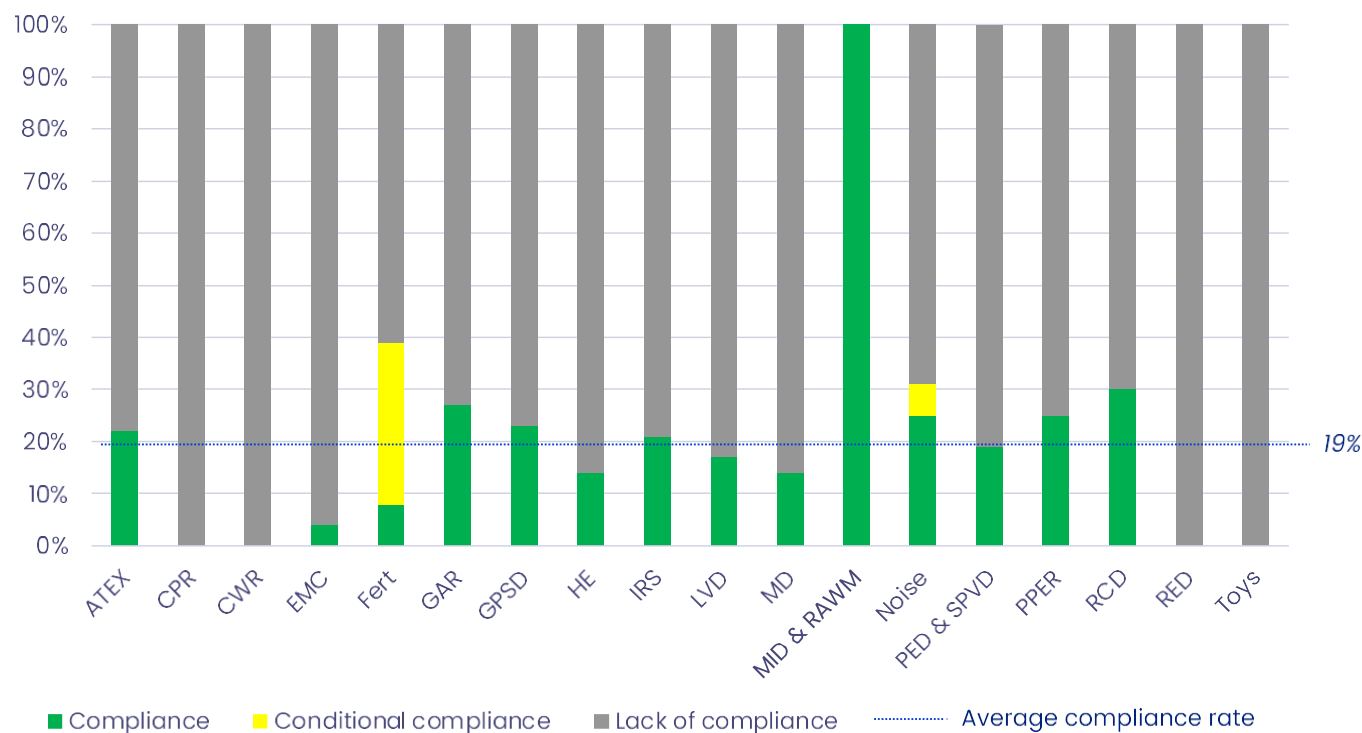
Source: CEN-CENELEC webinar on HAS process. Figures beyond 2022 may be available.

Much of this stems from a lack of legal clarity during the drafting phase, particularly in the **preparation of Annex Z**, which links standards to legal requirements. The process is overly complex and resource intensive. To address this, assessors should be involved earlier in the development process to clarify legal expectations and participate in building consensus.

In parallel, we propose the **creation of a dedicated cadre of 'Annex Z advisors,'** distinct from HAS consultants, who are trained to bridge the gap between legal and technical domains. These advisors would guide standardisation experts in drafting formally correct Annex Zs, reducing friction over time.[10]

Finally, all formal requirements for drafting Annex Z should be compiled into a single, user-friendly reference document. At present, experts must consult multiple regulations, guidance documents and templates totalling over 300 pages. This fragmentation wastes time and creates unnecessary barriers to participation.[11]

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[10] This is similar to the growing reliance on tax advisors, who are increasingly necessary to complete personal tax declarations due to the rising complexity of tax laws.

[11] For example, drafting an Annex Z for a medical device standard, an expert is expected to consult, at a minimum: the Standardisation Regulation; the standardisation request (C(2021) 2406 final) for the Medical Devices Regulations (Regulations (EU) 2017/745 and 2017/746); the Blue Guide (2022/C 247/01); all three parts of the Vademecum; the template for the Verification of Conditions; multiple Commission communications; and guidance documents from the Medical Device Coordination Group (MDCG). Combined, these resources exceed 300 pages, even before considering additional or sector-specific materials, representing an estimated 37–40 hours of preparatory reading.

No such thing as a free lunch

Standards do not come for free. They require significant time, expertise and investment to develop, particularly in a system based on consensus and technical excellence. Industry contributes to this public–private partnership with the expectation that harmonised standards will be cited in the Official Journal of the EU (OJEU), making them usable for legal compliance.

The uncertainty created by the recent Court of Justice ruling on access to harmonised standards must be resolved swiftly.[12] A clear and workable solution is needed to preserve alignment with international practices and avoid fragmentation in the global standardisation landscape.

A **funding mechanism should be introduced to support broad access to harmonised standards** whilst compensating copyright holders. One option is to create a shared-access fund, in which all beneficiaries – including the Commission – contribute, drawing inspiration from past EU frameworks such as the telecoms universal service funding model.[13]

Such a solution would strike a fair balance between public access and respecting copyright, ensuring the sustainability of Europe's standardisation model.

No need for a new agency

Proposals to create a new agency to oversee the three ESOs reflect a misunderstanding of where the true challenges in the system lie. Europe does not lack institutions but coordination, implementation discipline and the political will to make full use of the structures already in place.

A **new agency would add an additional bureaucratic layer, dilute accountability and duplicate functions** already performed by existing bodies such as the High-Level Forum, the Multi-Stakeholder Platform (MSP) and the Commission itself. Rather than improving outcomes, it would disrupt a successful public–private cooperation model that has delivered consistent value over decades. Moreover, centralising oversight in a new body could weaken the technical independence of the ESOs and stifle industry engagement at a time when expert-driven standards development is irreplaceable.

The priority should be to **strengthen coordination and technical capacity within the existing framework**. Better alignment between the Commission and Member States is essential to improve market surveillance and ensure coherent standardisation strategies. Coordination amongst DGs also needs to be enhanced to avoid siloed approaches.

Greater use should be made of technical expertise already available within the EU system. Agencies such as the Joint Research Centre (JRC) or ENISA can play a more active role in defining robust, fit-for-purpose criteria for harmonised standards.

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[12] Case C-588/21 held that harmonised standards cited in the OJEU are part of EU law and must therefore be publicly accessible. This ruling creates a fundamental tension with the long-standing model of standards development, where industry co-invests in producing high-quality specifications under copyright-protected frameworks.

[13] Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive), repealed by Directive (EU) 2018/1972 establishing the European Electronic Communications Code (EECC).

At the same time, research and innovation outputs must feed more effectively into standardisation. This means providing targeted support for researchers, ensuring relevant results are channelled into ESO workstreams, and reinforcing the link between EU R&I programmes and standardisation priorities.

The focus should remain on strengthening the development and citation of harmonised standards – including by aligning timelines in legislative acts, improving quality assurance processes and ensuring meaningful industry involvement at all levels.

FOR MORE INFORMATION, PLEASE CONTACT:

Omar Dhaher

Technical Associate Director for Standardisation & Compliance Policy

omar.dhaher@digitaleurope.org / +32 465 21 99 38

Alberto Di Felice

Policy and Legal Counsel

alberto.difelice@digitaleurope.org / +32 471 99 34 25

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