

SBS reply to the Call for Evidence for the revision of Regulation 1025/2012 on European standardisation

July 2025

SBS welcomes the opportunity to provide feedback to the call for evidence for the revision of Regulation 1025/2012 on European standardisation (from here on "The Regulation"). SBS welcomes the *"focus on ensuring that standardisation is accessible to EU SMEs and startups"* stated in the call, and highlights that this should be a primary policy objective of the revision.

The [report on the evaluation](#) and the [accompanying study](#) give an in-depth analysis of the state of the European Standardisation System (ESS) since the entering into force of the Regulation, highlighting many of its strengths and weaknesses. While SBS certainly agrees with the need to improve parts of the ESS, the evaluation at times seems to underplay certain nuances and the tangible improvements achieved since the entry into force of the Regulation.

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In particular the report focuses on shortcomings in three main areas, concerning specific policy objectives of the Regulation:

- Speed and market responsiveness in development of standards, particularly in the ICT sector;
- Further improvements necessary in the inclusiveness of the system;
- Strengthening the role of the ESS in international standardisation.

Accelerate and simplify standards development

The evaluation report acknowledges that *"the Regulation was moderately effective in increasing the speed of delivery of European standards"*¹, and SBS agrees that further efforts are needed to ensure a more agile and market-responsive standardisation system. Some changes, like the proposal to establish and systematically use machine-readable data formats, ensuring these formats can connect seamlessly with relevant communication systems, and shared online authoring tools to

¹ [EC Staff Working Document – Evaluation Regulation 1025/2012, p.67](#)

draft European standards outlined in [the Single Market Strategy](#), would provide an acceleration of the standards development process, with no downsides in terms of quality and inclusiveness.

Most commonly, however, speed in standardisation comes at a price: it means either less time to build genuine consensus, and properly consider the opinions of all stakeholders, or more flexibility in accepting the final outcome of the process of development of harmonised standards (hENs). SBS believes that speed should not come at the expense of inclusiveness or the ability of all relevant stakeholders, including SMEs, to engage meaningfully, in order to support the acceptance of standards and ensure high quality and SME-friendliness.

While there are certainly ways to streamline the rules and processes of the European Standardisation Organisations (ESOs), some additional ideas can already be put forward:

- Accept that Technical Specifications (TS), faster-developing and more flexible deliverables, could, in specific cases, help address Essential Health and Safety Requirements (EHSR) of European legislation and provide presumption of conformity. Such an approach may be particularly useful for SMEs operating in fast-paced sectors by enabling them to bring compliant products to market more quickly.
- To ensure that standardisation can effectively support legislation in a timely manner, it is important to consider the potential need for standards as early as possible – ideally from the moment a legislative proposal is issued. A useful approach could be to launch an initial standardisation request(SR) in parallel with the legislative proposal. There is precedent of an initial SR, requesting European standards, followed by a second SR requesting hENs, once the final legal text is available. This principle could be implemented more systematically, with the first SR published alongside the legislative proposal. This would allow standards to be already developed during the legislative process, drastically saving time.
- Map and assess existing standards, checking if they can be used or adapted to satisfy EHSRs across different pieces of legislation. This approach can help to speed up the process and avoid proliferation of standards.
- Speed up the citation of hENs by establishing transparent and binding procedures, with clear deadlines, criteria and justifications for delays. Additionally, establish stronger feedback loop and involvement by the HAS consultants during the development process. It is also essential to guarantee the continuity of the assessment system itself – avoiding disruptions, such as gaps in contracting arrangements, which have previously led to significant backlogs in assessment and delayed citation

Improve inclusiveness and balanced stakeholder representation

Tangible improvements in inclusiveness and effective stakeholder participation since the inception of the Regulation were highlighted both in the evaluation report and, particularly, in the accompanying study². This progress is largely due to Annex III of the Regulation, which identifies recognised representative organisations for stakeholder categories that are typically underrepresented or lack resources to participate in standardisation. These organisations are granted additional rights and prerogatives in the development of hENs and vis á vis the ESOs.

As the Annex III organisation charged with representing SME interests, SBS has seen [a consistent increase](#) in the number of experts financed, technical bodies and work items followed, particularly increasing work in standardisation areas [in support of EU policy priorities](#), particularly regarding the twin transition. In this way, SBS contributes to the vital role of standardisation in support of European competitiveness, particularly in digitalisation and sustainability. SME associations play a crucial role in helping micro and small enterprises access and effectively use standards. By ensuring that these companies – which often face significant technical and capacity challenges due to their size – or their representatives are actively involved in standardisation processes, standards can become more accessible, practical, and better tailored to their specific needs.

The role of SBS and the other Annex III organisations as a positive driver “for enhancing stakeholder participation in standardisation”³ has recently been reinforced across different Commission documents.

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That said, there is still room for improvement. SMEs and other stakeholders still face financial and capacity constraints to participate in standardisation both at national and European level, as well as severe challenges in terms of access and balanced participation in the system. These challenges are discussed at length in the [Report and Recommendations](#) for inclusiveness in standardisation at the national level produced by the High-Level Forum on European standardisation (HLF), for which SBS was the lead drafter.

In order to address these challenges, SBS stresses the need to:

- Amend and restructure [Art. 6.1 of the Regulation \(“Access of SMEs to standards”\)](#). Now this article consists of a non-exhaustive, non-binding list of measures that National Standards Bodies may take to support access and effective participation of SMEs in standardisation at national level. In practice, this has resulted in uneven conditions for stakeholders, particularly SMEs across different Member States; The existing list should be expanded to include the mentioned HLF recommendations, and the measures made mandatory.

² [Evaluation study of the regulation \(EU\) 1025/2012 on European standardisation, p.47](#)

³ [Interim evaluation of the Single Market Programme, p. 248](#)

- As emerged also in the findings of the HLF report, improve the level of strategic and political involvement of Member States in standardisation, and their ability and willingness to liaise with stakeholders, particularly SMEs and their representatives, active in standardisation.
- Ponder extremely carefully any expansion of the number of recognised Standards Development Organisations (SDOs) that may develop hENs. While diversification of SDOs may bring certain benefits, it could also lead to an excessive fragmentation and complexity of the system, with no guarantee that key principles such as openness, transparency, and inclusiveness will be upheld equally across all organisations. It is essential that any envisaged change explicitly safeguards the involvement of underrepresented stakeholders, including SMEs, and ensures that the current prerogatives granted to Annex III organisations are preserved or strengthened. Moreover, such fragmentation may place additional demands on already scarce resources making it even more difficult for SME representatives and experts to contribute meaningfully unless appropriate support mechanisms are in place.

Strengthen the EU's impact on international standardisation and funding of the ESS

SBS fully supports the European ambition to be a global standards-setter and appreciates the strategic approach to standardisation taken by the Commission since the 2022 Standardisation Strategy. SMEs have a strong role to play in this sense, if properly supported in their participation at all levels of the standardisation system, leveraging the national delegation principle.

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With regards to the role of European SMEs in international standardisation, a point of particular interest is the development of ICT technical specifications eligible for referencing under Article 13 of the Regulation. Ad-hoc funding for the participation of European SME experts *“in the development of ICT technical specifications that are not national, European or international standards”*⁴ should be pursued to ensure SME inclusion in the development of any specification or deliverable that might be adopted across the Single Market.

Any ambition of European leadership on the international stage must be accompanied by adequate financial backing. In particular with the upcoming negotiations on the new Multiannual Financial Framework, it is crucial to ensure robust and consistent funding for the ESS, across the different EU annual budgets. Past experience (eg: gaps in the financing of the HAS consultants system) has shown that breakdowns or interruptions in funding, however momentary, can have long-lasting negative effects on the functioning of the system.

SBS also stresses the importance of maintaining centralised funding for the ESS in one main financial envelope (currently the Single Market Programme – SMP), rather than dispersing it across multiple smaller financing streams.

⁴ [Regulation 1025/2012 on European standardisation, Art. 13.1](#)

Common specifications

SBS understands the need for an alternative fall-back option, in the form of common specifications, when requested harmonised standards (hENs) are not delivered by the ESOs. However, several areas of concern remain:

- In the absence of an established ad-hoc process for the development of common specifications, the comitology procedure under Regulation 182/2011 for the approval of implementing applies. This Regulation does not give sufficient guarantees towards stakeholder involvement since it does not set rules or requirements in terms of stakeholder participation in the drafting of an implementing act. Using comitology to adopt common specifications therefore risks bypassing the inclusive framework established by Regulation 1025/2012.
- Consequently, there is insufficient clarity on the mechanism for the gathering of input from different stakeholders in the development of common specifications. Any fallback option established by the Commission must guarantee the same level of access granted to stakeholders and their representatives under Regulation 1025/2012 and its Annex III.
- There is still a lack of clarity on the criteria to trigger the process of development of common specifications. So far only vague wording is provided, mentioning “*absence of requested standards*”, “*insufficient quality*” and “*urgent policy need*”, with no clear criteria and procedure.

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SBS reiterates that common specifications should only be considered as a last resort measure. The primacy of stakeholder-driven harmonised standards must be preserved as the main way to facilitate compliance and provide presumption of conformity, following a market-based and stakeholder-driven approach to standards development.

SBS believes that the wording allowing the development of common specifications under [Art.20 of Regulation 1230/2023 \(“Machinery Regulation”\)](#) would offer a tangible improvement. Specifically, Articles 20.3 and 20.4 give some needed clarification regarding the procedure and the fora to be consulted for the development of common specifications, and Article 20.5 clearly prescribes that “*The Commission (...) shall duly consult all relevant stakeholders*” in the development of the specifications.

Small Business Standards (SBS) is the European association representing and supporting small and medium-sized companies (SMEs) in the standardisation process, both at European and international levels.

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