Explanatory Paper

Revision of Regulation 1025/2012, December 2025

SFS Finnish Standards is a member of the European Committee for Standardization (CEN) and the International Organization for Standardization (ISO). As a National Standardization Body (NSB), SFS is committed to enhancing the European Standardization System (ESS) for a stronger Europe and improved competitiveness of every European country.

SFS agrees that the European Standardization System should be further developed. While the system has successfully supported the functioning of the internal market for over 30 years, it is due for an assessment of its future sustainability and development needs. When making improvements to the European system, it should be kept in mind that the system currently provides stability for European companies and all its stakeholders, and therefore any changes must be clear, widely discussed with stakeholders, and the time frame for the transition must be sufficiently long.

The European Standardization System requires targeted and sensible revision over the coming decades. Revision should maintain the system's founding principles while adapting to rapid digital change, new technologies, and global competition. The ESS must continue to uphold WTO values such as transparency, openness, impartiality, consensus, effectiveness, relevance, and coherence for reliable standardization.

Speed and responsiveness to innovation

The effects of Regulation 1025/2012 on the timeliness of standards particularly concern harmonised standards (hEN), which comprise about 20 % of European standards, leaving 80 % of European standards market-driven and without connection to a regulatory framework. Within market-driven standardization, the industry has had the opportunity to more quickly develop Technical Specifications and Workshop Agreements in addition to standards.

The unavailability or delayed availability of harmonised standards may be due to limited expertise, the need to ensure inclusivity and consensus-building, complexities in harmonisation processes, and citation requirements. It is important to understand the reasons why a harmonised standard has been delayed or is not available. For that reason, SFS proposes a transparent evaluation so that the process can be improved iteratively based on the principle of continual improvement.

To deliver harmonised European standards on time, SFS recommends that everyone involved in the development of hENs, including the EU Commission, CEN and CENELEC, and HAS consultants, work to speed up and simplify their processes and collaborate effectively for solid and future-proof process. This should be done without compromising inclusivity and the quality of standards.

Setting strict deadlines for technical committees and threatening penalties, as stated in question 37, will not help to achieve flexibility and speed but could discourage volunteer

experts and decrease participation. Offering incentives and recognition should be considered instead.

Early involvement by the Commission in the standardization process is beneficial, but there have been some cases where the Commission representatives have dominated technical discussions. This has led to a lack of consensus, which is a core standardization principle. HAS consultants' early participation in the process would also be beneficial for better defined standardization requests.

In certain technology domains, such as emerging or digital technologies, accelerated procedures can be valuable. However, in areas that involve fundamental safety considerations and where achieving broad consensus is essential, speed should not be the primary objective. SFS welcomes more than one track for harmonised deliverables, presuming that the principles of European standardization (transparency, inclusiveness, consensus) are in place.

Answering the second statement of question 37 is challenging, as it presents several options – some of which SFS sees worth considering while being more critical of others. SFS recognises opportunities in the more flexible ways (harmonised) standards are developed and delivered, including dedicated and simplified formats and procedures for (harmonised) standards requested in support of EU law. CEN and CENELEC and National Standardization Bodies as well as ISO and IEC generally use similar formats and have harmonised their guidelines. With Online Standards Development (OSD) and Smart Standards (SMART), additional digital requirements will be introduced in the future.

The use of alternative types of standardization deliverables with the presumption of conformity instead of standards is worth considering. Options like Technical Specifications, Workshop Agreements, and Technical Reports offered by CEN, CENELEC, ISO, and IEC can serve as initial steps toward a harmonised standard. CEN and CENELEC are also developing new types of deliverables such as European Agile Specifications (EAS), which can be especially valuable in emerging areas. Moreover, CEN and CENELEC are continuously enhancing their processes. The administrative timelines for standard development will be significantly reduced, ensuring that the essential consultation period required for expert consensus remains intact.

SFS is critical of the proposals for recourse to other standardization bodies and open calls procedures for obtaining standards. If other organisations are assigned to create standardization outcomes that form the basis for presumed conformity, it could jeopardise the unity of the European Standardization System. Furthermore, the link to international standardization – ensured by the European Standardization Organisations (ESOs) – would be threatened as well. There would also be more competition among different groups for the limited pool of experts available to draft standardization documents. As a result, compliance and guidance costs would rise considerably, particularly impacting SMEs.

Opening Annex I to additional organisations may also threaten the integrity of the European Standardization System. Moreover, the existing European standardization organisations play a crucial role in maintaining ties with international standardization, which could be endangered by such changes.

If the standardization framework is opened to allow other organisations or consortia to respond to specific standardization requests alongside the recognised ESOs, conducting this process through European Standardization Organisations would be essential to maintain the integrity of the European Standardization System and ensure its alignment with international frameworks. To uphold this, CEN and CENELEC are further opening their system to constructive cooperation, positioning themselves as a true “European standardization hub”, that is a central integrator of high-quality standards content developed in line with European interests, values, and regulatory principles.

Inclusiveness of the standardization process

Inclusiveness in European standardization is delivered through the national delegation principle, which is fundamental. At the national level, the composition of stakeholders within the standardization committees remains transparent and accessible.

SFS is committed to enhancing stakeholders’ participation in standardization. SFS is developing a clear participation pathway and actively monitoring as well as developing the analysis of the extent of stakeholder involvement. In addition, SFS Comment Portal allows anyone to review and comment on draft standards without the need to join a standardization committee.

SFS, along with two other National Standardization Bodies, SESKO and Traficom, have actively advocated for the adoption of a national standardization strategy, as strategic use of standardization is less common in Finland compared to many other countries. The Ministry of Economic Affairs and Employment of Finland has recently initiated this strategy work.

In question 44, measures such as financial support or free access to improve inclusiveness and stakeholder participation should be considered separately. SFS is in favour of financial support but against free access. It is important to provide financial support for SMEs as well as civil society so they can participate in standardization projects, especially at the national level where barriers to getting involved are lower. However, financial support should not undermine the ability of standardization organizations to fund their non-profit activities. As a result, the concept of "free access" should be rejected.

Training programmes for standardization experts are essential to attract new talent and strengthen Europe's role in global standardization. To this end, CEN offers relevant seminars, while SFS promotes standardization in national education and training. SFS also co-operates with higher education institutions to increase awareness and use of standards.

Not all standards apply to SMEs. For this reason, rejecting the demand for an obligation on ESOs and NSBs to ensure a minimum share of SME representatives in technical committees (question 44) makes sense. Instead, it is more valuable to utilise tools such as the public standards draft portal that enables stakeholders to easily access information and participate in topics that are important to them. Relevant stakeholder groups involved in technical committees for a particular standardization project should be based on the topic of the standard.

CEN and CENELEC are membership-based organisations, where voting rights are reserved exclusively for members. Extending voting rights (question 44) to individual interest groups within the standardization process would jeopardize the consensus principle and contravene WTO criteria.

It is important to raise awareness of standardization and lower the threshold for participation in standardization. AI-based standardization assistants are encouraged; however, it is essential for National Standards Bodies (NSBs) to ensure that the development of such tools aligns with NSB copyright and copyright regulations. Additionally, it is crucial that stakeholders, including industry associations and chambers of commerce and industry, recognise the advantages of standardization and actively promote its adoption among SMEs as a means to enhance growth and competitiveness.

National Standardization Bodies offer optimal support for inclusive stakeholder participation. SMEs, start-ups, and representatives of consumers or civil society are generally able to engage in standardization processes more readily at the national rather than the European or international level thanks to lower travel expenses and fewer language barriers.

Efforts to enhance inclusivity should not compromise the fundamental principles or quality of standardization. The adoption of best practices across Europe should be encouraged and supported.

Access to standards

European standards, whether market-driven or harmonised, are developed by volunteer experts from various stakeholder groups such as industry and public sector operators, research organisations, and civil society. The system is primarily funded through private revenue from standard sales; for instance, 80 % of SFS's funding in 2024 came from sales.

European and international standards alike are protected by copyright. Copyright ensures the quality, traceability, and long-term sustainability of standards. It is an essential prerequisite for the European Standardization System.

The legal aspects of harmonised standards need to be considered thoroughly. Changes in the legal framework of European Standardisation System – such as the use of common specifications when hEN’s are not available – necessitate impact assessments. Insufficient impact assessments may result in consequences that negatively affect European industry and compromise the integrity of the single market.

Regarding questions 46 and 47 addressing the legally relevant content of harmonised standards, SFS would like to clarify the following aspects: firstly, the future digital developments and machine-readable standards will improve on the current structure of standards. Currently Annexes ZA (CEN) and ZZ (CENELEC) clearly show the relationship between legal requirements and the content of standards. Secondly, SFS strongly disagrees with the proposed idea that having several alternative harmonised standards for a certain purpose would be beneficial. Multiple and potentially competing standards require extra effort to navigate, particularly for SMEs, and create unnecessary challenges. Such diversity of standards can also threaten the consistency of the European Standardization System and complicate market access, especially for SMEs.

In question 47, SFS would like to draw attention to the wording of the first and fourth statements.

The first statement "*The legally relevant content of standards should be published and freely accessible by default*" extends beyond the recent judgements (e.g. ECJ 588/21P), because it mentions standards in general and not harmonised standards. Even when providing access to the legally relevant content of harmonised European standards, appropriate financial compensation remains necessary.

The fourth statement "*Accessing only the legally relevant content of harmonised standards in the OJEU is sufficient for my work*" is misleading. The Official Journal of the EU only publishes references to European standards, not the full texts. The statement anticipates that the actual content should appear in the Official Journal, which would clearly infringe on copyright and require proper compensation. Additionally, publishing the legally relevant parts of hENs in the Official Journal could introduce the risk of outdated standards being used.

EU's role in global standard-setting

Approximately 54% of Finnish exports are to EU countries and 46% to other countries (2024). The more uniform European and global standards are, the more companies operating in the export markets of a small export-led country, such as Finland, will benefit.

The Vienna and Frankfurt agreements have largely ensured that there are no European standards that differ from global standards, and this makes access to global market easier for European companies. These agreements also enhance efficiency and resource utilisation for stakeholders, enabling them to contribute their expertise and shape outcomes through a singular, streamlined process.

Global standardization (ISO, IEC) is conducted in accordance with the national delegation principle. This 'one country and one vote' principle enables European countries to have equal influence – according to their own requirements – in global standardization, provided that European countries are actively involved.

The Commission's goal is to enhance Europe's voice in global standardisation. SFS shares this goal and to help reach it, encourages the Commission to continue its open and forward-looking collaboration with ESOs and EU member countries as well as other like-minded European countries. A definition of the technology areas where the promotion of expert participation in standardization should be prioritised should not be centrally determined by the EU Commission but rather in conversation with industry representatives.

The national delegation principle is significant and well-functioning especially from the SME's perspective, and as such, SFS strongly supports it.

Conclusion

The revision of regulation 1025/2012 presents new opportunities to boost Europe's competitiveness and economic growth. As part of this shift, it's crucial to assess how standardization affects both the internal market's operation and the competitive standing

of companies and EU member states. While there is the possibility of offering free access to harmonised standards in the future, developing these standards will still require funding to cover their production costs.

Because the standardization system brings substantial benefits to Europe, any modifications to it should be approached with careful consideration. Any changes to the system should be made thoughtfully and cautiously, making sure to uphold the core values of openness, transparency, inclusiveness, and consensus.

SFS Finnish Standards

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