

"Shaping the Future: A New Era for European Standardization"

Response of CEN and CENELEC for the Call for Evidence on the Revision of Standardization Regulation 1025/2012

Introduction

European standards (ENs) play a crucial role in advancing strategic priorities. By setting harmonizing practices, they can support economic growth, innovation, sustainability, and geopolitical influence:

- 1. Promoting economic integration: ENs facilitate cross-border trade by ensuring compatibility and reducing technical barriers. This strengthens the Single Market and European competitiveness.
- 2. Driving and enabling innovation: By establishing standards for emerging technologies, ENs enable innovation while ensuring safety, reliability, and interoperability.
- 3. Advancing sustainability goals: Standards encourage the adoption of environmentally friendly practices, such as energy-efficient processes and sustainable construction.
- 4. Strengthening global influence: When ENs gain international recognition, they help bolster the EU's strategic position as a leader in regulatory frameworks.
- 5. Supporting resilience and security: Standards are essential in areas such as cybersecurity, energy infrastructure, and healthcare, ensuring robustness and preparedness in critical sectors.

CEN and CENELEC, two of the European Standardization Organizations (ESOs), together with our Members the National Standardization Bodies (NSBs) and the National Committees (NCs), see the revision of the Regulation 1025/2012 as an opportunity to reinforce the role of the European Standardization System (ESS) and anchor it in an ever-evolving reality. We offer an experienced and trusted system from which we can support Europe in achieving global economic leadership.

Key Messages

- 1. Achieving Timely Standard-Development and Citation in the Official Journal of the EU
- **Devising innovative solutions**: Since our creation, CEN and CENELEC, and our Members, have been constantly adapting to address the changing needs of the European market and regulatory context. Today is no exception and we are currently working on new quick and flexible solutions that maintain our core values: openness, transparency, consensus and inclusiveness. These principles remain essential and must now be applied in new ways. We are reviewing our standards development processes and actively working to accelerate standardization while upholding its integrity. In Annex 2, you will find CEN and CENELEC data reporting the time taken for the development of standards.
- Investing in new technologies: CEN and CENELEC are investing into new technologies to future proof the ESS. Two key projects are Machine-Readable Standards (SMART) and Online Standards Development (OSD). SMART standards will allow us to offer a more innovative deliverable to standard users, recognised by the Single Market Strategy as an essential

evolution in European standardization. OSD provides the opportunity for the Technical Committees to use a collaborative authoring online solution, which can enable faster progress on documents, by reducing the time spent for providing and resolving comments. Both projects are developed in cooperation with our international counterparts, ISO and IEC.

- **Timely citation in the OJEU:** For economic actors, especially in strategic sectors subject to fast innovation cycles, the timely availability of harmonized standards (hENs) is crucial. The steps involved in the development of the hENs (including EC compliance assessments and citation) significantly affect availability. For example, the time needed to cite a standard in the OJEU is approximately 11 months¹. As CEN and CENELEC develop solutions to speed up standards development, the EC should implement measures to improve the speed of citation. In Annex 3, we provide some concrete suggestions on how this could be achieved.
- **Implementation of the ESOs-EC TF Measures:** the EC and the ESOs Joint Task Force has worked to address bottlenecks in the timely availability of hENs. It concluded with several recommendations, such as a Common Checklists for Standardization Requests, a Centralised CEN and CENELEC Quality Check, and a clear timeline for the EC to deliver a final assessment. The EC and ESOs should continue to capitalise on these improvements and ensure that the revision of the Regulation 1025/2012 does not undo this progress. See Annex 1 for more information.

2. Tap in the potential of all standardization deliverables

- **Using other deliverables:** CEN and CENELEC offer a wider range of deliverables, from hENs directly compliant with WTO/TBT principles to technical specifications, that fulfil the needs of a variety of stakeholders and provide timely compliance. These deliverables combine flexibility in consensus and time required for their delivery, allowing ESOs to respond to new technologies and market needs. The impact assessment should clarify which CEN and CENELEC deliverables best support legal requirements. To complement our current offering, we are also developing a streamlined deliverable designed to address urgent needs. It will combine agile development by experts representing European interests with a lightweight ratification process, ensuring rapid deployment while maintaining consensus at European and national level.
- **Technical Specifications (TS):** TS offer consensus and a quick development process, meaning it can be an alternative to a hEN. They serve as normative documents when the state of the art is not sufficiently stable for an EN. TS are developed following WTO and national delegation principles. It takes on average 24 months from initiation to publication but can be developed in 18 months.

¹ European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fraunhofer ISI, Intellera Consulting, Trinomics B.V, Bianchini, D. et al., Evaluation study of the regulation (EU) 1025/2012 on European standardisation – Final report, Publications Office of the European Union, 2025, https://data.europa.eu/doi/10.2873/2178479

- For example, CLC/TS 50600-5-1 was the first normative approach set globally on data centre maturity models for energy efficiency and environmental sustainability.
- **Technical Reports (TR) and Guides:** TR provide guidance on standards and help users have a shared understanding of technical requirements. Guides provide recommendations on standardization principles and policies to address issues relevant to standard users. TRs and Guides are developed within 20 months.
 - For example: CEN/CLC/TR 17912:2023 maps relevant standards on hyperloops, providing a valuable tool for industry and regulators in this emerging field.
- Workshop Agreements (CWA): The CWA provides a fast track for future standardization. It is developed in a temporary setting with direct participation of all interested. CWAs enhances interoperability, market uptake and innovation. Popularity has increased due to its quick development time of 10-12 months.
 - For example: CWA 17553:2020 was developed in response to the urgent need Covid-19 created to provide necessary guidelines on community face coverings.

More detailed information on these deliverables can be found in Annex 4.

- 3. Strengthen Europe's role and impact in international standardisation.
- Standards for global markets: Global technology leadership is paired with standardization. European industry strongly benefits from international alignment in standardization, allowing for global market access and reduced costs as products do not have to be manufactured differently for different markets. Through the Vienna² and Frankfurt³ Agreements with ISO and IEC, Europe has the unique ability to give priority to cooperation with ISO and IEC provided that international standards meet European legislative and market requirements. For standardization experts, this ensures the best use of resources while preventing duplication of work when preparing standards.
- Strong European presence in ISO and IEC: Via their participation in ISO and IEC, the • National Members of CEN and CENELEC ensure that European expertise has impact internationally. Only through active participation and coordination in international standardization can Europe place itself as a global leader in strategic topics like fuel cell technologies, circular economy, cybersecurity, or quantum technologies. The unique advantages that the Vienna and Frankfurt agreements offer Europe must be confirmed and strengthened by the revision of Regulation 1025/2012.
- 4. Strengthening the European Single Market through a clear legal framework for the use of European Standards
- Standardization for an Effective New Legislative Framework (NLF): The NLF has been key to the success of the Single Market. Its main benefit is legislators set out essential

 ² <u>Vienna Agreement, 1991</u>
³ <u>Frankfurt Agreement, 2016</u>

requirements, while the technical specification of these requirements is carried out by experts in the technical committees of the ESOs. This division of responsibilities ensures those with knowledge of innovation and market needs shape hENs. The specialist knowledge that experts contribute to standardization is put to optimum use, and the legal framework remains efficient. If the state of the art evolves, only the standard needs to be revised, not the underlying law. A coherent and trusted standardization system is essential for competitiveness. Any proposal for additional ESOs should consider increased coordination costs, the risks of fragmentation in the development of standards, and compromised international alignment.

- ENs at the heart of the European quality infrastructure: The value of standardization lies in its technical and voluntary nature. By improving product safety and quality, standards build trust between market participants and reduce transaction costs. ESOs not only provide the standards against which products are assessed, but also the standards for the architecture of the quality system itself, e.g. EN ISO/IEC 17011 on the requirements for accreditation bodies. Without these standards, the European and national quality infrastructures could not perform their activities. Standards should be continued to be recognised as an essential element of the European quality infrastructure.
- **Common Specifications:** We understand the need for a fall-back option, but we urgently require more clarity. The proposed Omnibus article on common specifications has less conditions on when the EC can use this fallback option than Article 20 of the Machinery Regulation. The Article 20 model has been widely used in recent legislation, e.g. the AIA, the CRA, the provisional agreement on the Toy Safety Regulation (Article 14), etc. Thus, there will be inconsistencies between these legislations and those targeted by the Omnibus. The Omnibus article should be similar to the Article 20 of the Machinery Regulation or Article 14 of the Toy Safety Regulation on common specifications for the following reasons:
 - The Omnibus omits the need to initiate a standardization request, focusing just on the absence of a hEN. This may lead to common specifications without prior ESOs engagement.
 - There is a repeal mechanism in the Machinery Regulation that is absent in the Omnibus.
 - In the Machinery Regulation, the Commission shall consider the views of relevant bodies and duly consult all relevant stakeholders. This is not present in the Omnibus proposal. However, broad participation in the development of technical specifications is an essential prerequisite for their acceptance on the market.

It is also unclear on how exactly common specifications will be developed and how their development would ensure transparency and widespread industry acceptance.

• **Coherence of the ESS:** The Commission is considering the use of standards from sources other than the ESOs as well as developing common specifications. CEN and CENELEC propose that standards from outside the ESS should be subject to the same requirements as standards developed by the ESOs, namely WTO principles and requirements from the standardization regulation, including requirements for inclusion of Annex III. The criteria for selecting ESOs standards vs alternatives should be transparent. The cost of developing common specifications and acquiring of standards from other organisations should be considered in the upcoming

impact assessment. As of now, no data has been made available on this. The use of common specifications and standards from outside the ESS risks a proliferation of competing technical requirements on the European market and a less coherent ESS.

- 5. <u>Access to Harmonized Standards: Embracing free readability while upholding the importance</u> of copyright & intellectual property
- Supporting the Commission to implement the ECJ ruling: Free readability access to harmonized European standards is an important step forward. However, this transition must be carefully managed to preserve the integrity and sustainability of the ESS, in particular the financial sustainability of NSB and NCs must be preserved to ensure European leadership at international level. CEN and CENELEC Members are well-positioned to lead this transition by using their established national platforms to efficiently support access to harmonized standards at the local level. Future developments in digitalization will make it possible to enable easier understanding and access to those sections of hENs directly related to legal requirements.
- **Protecting intellectual property (IP) is essential:** Copyright of harmonized standards lies with the ESOs and upholding existing IP rights is essential to protect the financial sustainability of the standardization system. Copyright enables NSBs and NCs, many of which are not-for-profit, to develop value-added products and services that facilitate implementation, generate revenue streams, and support long-term sustainability. Appropriate and proportionate remuneration should accompany free readability access to standards. Through collaboration with the European Commission, CEN and CENELEC, with our Members, are working to ensure hENs remain a tool for simplification, quality and safety within the internal market.

6. Fostering inclusiveness and wider stakeholder participation

- **Maintaining the essential values of standardization:** As Europe looks to accelerate standardization, it is essential to preserve the time needed for meaningful consensus-building. Faster processes must not come at the expense of quality, inclusiveness, trust or weakening of the national consensus model. Streamlining can go together with maintaining the integrity of the system that underpins European competitiveness and confidence in European standards.
- The crucial role of the NSBs and NCs: NSBs and NCs guarantee fair, balanced, and expertdriven standards development. These national processes promote diversity of input and stakeholder balance, reinforcing both legitimacy and technical quality. NSBs and NCs act as crucial links between national stakeholders and the European level as they channel input from the national level to the development of European standards.
- **Promoting an inclusive system:** CEN and CENELEC are committed to an inclusive system involving a broad range of stakeholders, including SMEs and societal actors. This commitment goes beyond the provisions of Regulation 1025/2012. Two advisory bodies within our governance have been created, the SME-Working Group (SME-WG) and Societal Stakeholder Group (SSG), to address the needs of these stakeholders. They are currently focused on the

implementation of the recommendations from the European High-Level Forum (HLF) on standardization workstreams on inclusiveness at national, European and international level. The establishment of the opinion mechanism has also enhanced the SME and societal stakeholders' voice when developing standards. In 2024, Annex III submitted 77% favourable opinions. CEN and CENELEC value our continued collaboration with ANEC, ECOS, ETUC and SBS to identify new measures to increase inclusivity in the European standardization process.

• Fostering new generations of standardization experts: NSBs and NCs have cultivated a strong network of 200,000 technical experts from industry, SMEs, public administrations, academia and societal organizations. However, like in many sectors, securing expertise is a major challenge. While there are many initiatives to improve the availability of expertise, the revised Regulation should acknowledge the importance of integrating standardization into vocational education and university curricula. This will benefit the recruiting of future experts.

Conclusion

CEN and CENELEC acknowledge the challenges presented by shifting geoeconomic dynamics, and Europe's need to leverage emerging technologies to stimulate competitiveness. To find solutions, we commit to working together with the European Commission for an advanced ESS and to boost changes already underway e.g. digitalization and improving the timely availability of standards.

ANNEX 1: The EC-ESOs Taskforce

Implementation measures identified in the ESOs-EC TF elaborated

The European Commission and the ESOs invested time and resources in a joint Task force to address bottlenecks for the timely availability of harmonized standards, which finished its work in 2023 with the identification of several concrete measures, such as:

- Checklist for Standardization Requests: Designed for ESOs to bring to the EC's attention any critical elements that could jeopardize the feasibility of the draft Standardization Request (SReq). It is now systematically attached to any SReq submitted by the EC to the approval of the Committee on Standards.
- Checklist for hEN assessment: A new common checklist for the assessment of harmonized standards to be used by the ESOs, EC's consultants and EC officers to avoiding misinterpretations of potential noncompliance, which has systematically been in use since 1 October 2023.
- Centralised quality check: A new service performed by CEN and CENELEC secretariat to check the drafts developed by experts before their submission to EC assessment. More than 300 quality checks have been performed so far.
- Brand new process for European homegrown harmonized standards, connected with the above quality check and with an early exchange with the consultants, to align legal elements with technical content of the standard
- Clear timeline for the Commission to deliver final assessment before citation, to avoid unnecessary delays between the ESOs offering of hENs and their citation by the Commission.
- The EC and ESOs should continue to capitalise on the time and effort dedicated to these improvements and ensure that Revision of 1025 does not undo this progress.

ANNEX 2: Time needed to develop ENs and hENs

In the Commission Staff Working Document on the Evaluation of Regulation (EU) No 1025/2012 on European standardization, the following table is presented concerning the time for the citation of a harmonized standard, from Standardization Request until final citation in the OJEU. (The title of the table below 'average duration of standard development' is misleading because duration of standard development, i.e. indicated below as 'drafting stage' is only a part of the process).

		Baseline (before the Regulation) determined in the evaluation study		After the Regulation
Phase	Subphase	Low estimate	High estimate	(assessed in 2024)
Phase A: adoption & notification of standardisation request	Standardisation requests adopted by the European Commission	0.8 year (9 months)	0.8 year (9 months)	1.7 years
Phase B: Delivery of the standard	Acceptance of standard request by the ESOs	0.7 years (5 months)	0.7 years (5 months)	0.1 year (1 month)
	Drafting stage	2.7 years	5 years	3.1 years
Phase C: Submission and publication	ESO submission to the European Commission	5.4 years	5.4 years	0.3 years (3 months)
	Citation time in the OJEU	Not available	Not available	0.9 years (11 months)
Total		9.6 years	11.9 years	6.1 years

Table 4: Pre/post Regulation 1025/2012 comparison of average duration of standard development at the request of the Commission. Source: Evaluation study, Section 4.1.1.1

For homegrown hENs, which have been published in 2024, indeed it takes 3.1 year to complete the process. For hENs developed with ISO and IEC, the average development time increase to 4.4 years. When comparing ENs that are not harmonized with hENs, development time decreases to 2.6 years for

homegrown and 2.7 for those based on ISO and IEC. The decreased development time for ENs that are not harmonized is likely explained by the absence of intervention from European Commission consultants and the absence of the centralised quality check.

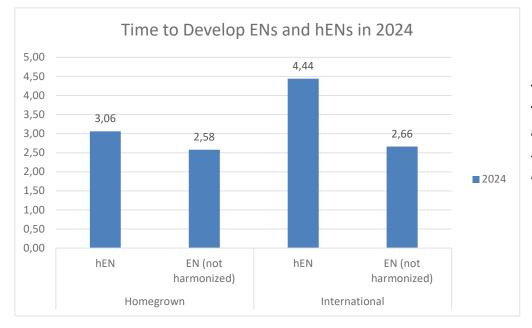


Table for DevelopmentTime in years of ENsand hENs in 2024.Source: CEN and CENELECData

Annex 3: Proposals to improve speed across the whole harmonized standard development process

The evaluation shows that issues persist regarding the how fast hENs are available in the market. The evaluation suggests an average of 6 years which includes three phases:

- A: EC adoption of standardization request (no defined time limit, responsibility of the EC and the ESOs)
- B: Acceptance by ESOs and drafting (time limits for ESOs, responsibility of the ESOs)
- C: ESO submission and EC citation (no defined time limit, exclusively the responsibility of the EC)

The lack of deadlines for phase A and C adds to processing variability and delays. According to the study, the lack of targeted durations could lead to unpredictable extensions in processing times.

The NSBs and ESOs are responsible for the B phase while the speed of phase A and C heavily relies on collaboration between EC and the ESOs. The ESOs can in that sense not decrease the time spent in phase A and C without the collaboration of the EC. As the decision to publish or reject harmonized standards ultimately lies with the Commission, we suggest improved dialogue in this field.

We suggest the following changes to the regulation:

Phase A:

- Article 10(1) should contain a maximum timeframe for development of SREQs including the SRAHG process.
- The SRAHG process, where dialogue between relevant experts and the EC takes place, should be continued.
- In cases where time is of essence, the European Commission can issue standardization requests before the legislative act is finalised, based on already established key essential requirements. Standardization experts can also contribute before the final adoption of legislative proposals by giving insights on state-of-the-art and technological developments to make sure that SREQs are up to date and remain open for innovative solutions. These best practices were used to support the development of standards in relation to the AI Act.

Phase B:

• CEN and CENELEC is acutely aware of the need to ensure that standards are available in the market faster and the need to develop new types of deliverables. This is particularly true for standards covering new technologies and the digital field. CEN and CENELEC are currently working on proposals which will speed up our processes and develop new, faster deliverables as described in the above section on Speed.

Phase C:

- Article 10(6) should introduce a maximum processing time for the Commission of, for example, three months from receipt to publication in the OJEU.
- An annual report from the Commission on processing times should be considered.
- Transparent and earlier involvement of HAS consultants, implementation of a supplementary quality control procedure to detect risks sooner.
- Article 10(5) should include a requirement for increased dialogue between the ESOs and the Commission in the development of harmonized standards. In addition, it is important that ESOs have resources to build internal capacity to guide experts in the development of HENs.
- Transparency of timelines of the HAS consultant's work can be improved significantly with increased transparency and timelines e.g. if the responsible TC is informed of the date of feedback from HAS, they can plan accordingly and resolve comments immediately after receiving feedback instead of waiting up to 6 months for their next meeting.
- A consistent funding to the HAS-system will prevent the standstill of the approval processes due to for instance new public procurement processes.
- These proposals align with stakeholder feedback in the Evaluation Study, where 58% of respondents found the Commission's citation requirements burdensome.

Annex 4: CEN and CENELEC Deliverables elaborated

Technical Specifications: Faster solutions to test the market

An alternative to a European Standard is a **Technical Specification** (TS), which offers the reassurance of a good level of consensus in its development balanced with a process that enables a market need to be met swiftly, particularly in areas where there is no immediate need for full national implementation.

Typically, the TS can serve as normative document in areas where the actual state of the art is not yet sufficiently stable for issuing a European Standard, in anticipation of future stronger harmonization, or for providing specifications in experimental circumstances and/or evolving technologies with lower Technology Readiness Levels. However, its role within the European standardization system is constantly evolving, as nowadays Technical Specifications are also developed in support of EU legislation, at the request of the European Commission.

Just as European Standards, Technical Specifications are developed within Technical Committees of experts and follow the same WTO and national delegation principles.

With its streamlined process, a TS takes on average 24 months from initiation to publication, though can be developed in 18 months. CEN and CENELEC Members announce TSs and make them available. TSs do not have to be fully implemented at national level but cannot conflict with any European Standard. If a conflicting EN is subsequently published, the TS is withdrawn, ensuring the coherence of the standards catalogue.

Similarly to ENs, Technical Specifications are reviewed systematically within the five years of their publication.

Technical Reports and Guides: Fast, non-normative solutions to support the users

- **Technical Reports** (TR) provide information and guidance on identified Standards. More specifically, they help users have a shared understanding of the technical aspects and requirements presented in those Standards, and thereby facilitate collaboration among all actors (industries, experts and end-users).
- **Guides** provide orientation, advice, or recommendations on standardization principles and policies. They offer guidance to standards writers and address issues relevant to users of European Standards, such as manufacturers, designers, service providers, and educators.

These types of documents are usually developed within 20 months and, once issued, do not bring any implementation obligations for the Members.

The Workshop Agreement: Faster and agile solution to meet the market needs

The **Workshop Agreement** (CWA) is designed to meet an immediate need and to provide a fast track to future standardization activities. It is developed in a temporary setting i.e. a Workshop, with direct participation of anyone interested in the subject.

CWAs are typically developed in innovative markets, where there is often a request for a reference document to be quickly developed as a stepping stone to standardization deliverables, to facilitate interoperability and compatibility, enhance market uptake of innovative solutions and facilitate further incremental innovations in the market.

CWAs are also particularly attractive for European research and innovation projects, which have to deliver results within the limited duration of their project lifetimes. European Framework Programmes like Horizon Europe focus more and more on the impact of research and innovation in developing, supporting and implementing EU policies, and support the uptake of innovative solutions in industry and society to address global challenges. Standardization, through the well-suited solution CWA, is a tool to support this strategic objective.

Over the years, the popularity of the CWAs has steadily increased (ca. 400 in the current portfolio), due to its quick and flexible development (10/12 months).

A CWA carries no obligation at national level for the CEN and CENELEC members.

Since 2017, CWAs in the R&D and ICT domains have been made publicly available on the CEN and CENELEC <u>website</u>.