

# Position Paper

## Elaboration on answers to the public consultation on Regulation 1025/2012 July 2024

### Executive Summary

To elaborate on the answers provided to the public consultation on Regulation 1025/2012, CEN and CENELEC:

- Emphasise that for the past 12 years, Regulation 1025/2012 on European Standardization has supported CEN and CENELEC in providing an open, transparent, and robust system that develops high-quality standards that support the European Single Market.
- Note that when assessing Regulation 1025/2012, one should differentiate between the regulation itself and its implementation. The latter is subject to improvements and if shortcomings are identified, the European Commission should consider an amendment rather than a full revision of the Regulation.
- Reiterate that the Vienna Agreement and the Frankfurt Agreement are the practices that ensure European members continue to have a pioneering role in international standardization.
- Note that standardization is a technical and voluntary matter that should not cross the line into legislation

### Effectiveness of Regulation 1025/2012

For the past 12 years, Regulation 1025/2012 on European Standardization has supported CEN and CENELEC in providing an open, transparent, and robust system that develops high-quality standards that support the European Single Market. The regulation facilitates effective collaboration between CEN and CENELEC, National Standardization Bodies and National Committees, the European Union/EFTA and Member States, reinforcing the strength of this public-private partnership. The provisions of the Regulation provide the necessary framework

needed to deliver standards in support of European Union policy, including harmonized standards requested by the European Commission. Regulation 1025 has contributed to the greater involvement of civil society and SME stakeholder participation through Article 5, which supports Annex III organisations through European Union funding.

Regulation 1025 supports the ability of European Standards to act as catalysts for innovation, enabling the rapid integration of emerging technologies. It does so by fostering the cooperation between all parties (ESOs, the European Commission, EFTA, Academia, Civil Society, SME and Industry) to ensure standards developed in support of EU policy meet the legal requirements and represent the views of many stakeholders to ensure wide adoption. CEN and CENELEC are dedicated to meeting the challenges of an evolving standardization landscape and undertaking initiatives to do so, for example, supporting the development of SMART Standards (machine-readable standards).

Standards cannot be developed without a considerable investment of resources in expertise, consultations, administration, translation, among other processes. This intensive work leads to the original, robust, and innovative solutions captured in the voluntary standards. To support the integrity of these efforts and ensure the sustainability of the standardization systems of CEN and CENELEC, it is paramount that intellectual property rights of standards are respected and upheld. Considerable attention must be devoted to the copyright protection of standards and other deliverables.

## **Speed and Timeliness of Standards Development**

### **Implementation of Regulation 1025/2012**

When assessing Regulation 1025/2012, one should differentiate between the regulation itself and its implementation. The latter is subject to improvements, especially the time required for developing harmonized standards. While addressing shortcomings are crucial, the most suitable approach involves improving communication, resource allocation, and mutual understanding within the public-private partnership between the European Commission and CEN, CENELEC and ETSI framed by the current Regulation 1025/2012. If shortcomings are identified, the EC should consider the use of an amendment to Regulation 1025/2012 rather than a full revision of the Regulation.

Regarding the question "*Considering the need for the ESS to adapt to a rapidly changing environment and support the EU's strategic goals, what action areas do you consider essential?*", CEN and CENELEC would like to elaborate on our response. CEN and CENELEC agree it is important to meet future standardization needs through the expedition of the standardization development process, but we must clearly identify which aspects need improvement.

### **Harmonized Standards Assessment (HAS)**

CEN and CENELEC emphasise that one area causing the delayed adoption of harmonized standards (hENs) concerns timely citation of standards in the Official Journal of the European Union (OJEU) and delays introduced in the HAS consultant assessment.

This has a negative impact on the hENs developed under Vienna and Frankfurt agreement. In 2023, the average time between the offering of a standard for citation and its publication in the OJEU was 393 days. Timely citation of harmonized standards is crucial as cited standards can be used by companies to facilitate presumption of conformity with EU legislation in a coherent and cost-efficient manner. When hENs are not cited in a timely manner, manufacturers face additional costs to comply with the diverging requirements on the European and international level and are deprived from using market-driven voluntary harmonized standards to demonstrate compliance.

The harmonisation and citation process are not described in the Regulation but rather are a result of its implementation. Any issues should be therefore resolved without a revision of the Regulation. According to Article 10(5), ESOs and the Commission shall jointly assess and decide whether the documents produced are in conformity with the standardization request. The European Commission and CEN and CENELEC have worked on the issue through the ESOs-EC-EFTA task force to find solutions to clarify the procedures. This initiative, which was a successful example of the public-private-partnerships, should be evaluated and continued if found useful.

To facilitate better processes and introduce more transparency for all parties, a cap on the Commission's processing time for publication in OJEU (e.g. three months) and annual reporting for the harmonisation process could be introduced. To support this, it is important that the European Commission and the HAS consultants have the necessary resources to carry out assessments.

## **Competitiveness of European Business at global level**

### **The Vienna Agreement and Frankfurt Agreement**

The members of CEN and CENELEC play an important role in promoting global competitiveness through participation in ISO and IEC. This participation in international standardization is facilitated by the Vienna Agreement between CEN and ISO and the Frankfurt Agreement between CENELEC and IEC. These agreements support market access outside Europe and encourage CEN and CENELEC members to develop international standardization deliverables. CEN national standardization bodies and CENELEC national committees actively contribute to shaping and utilizing international standards. Of the 2080 CEN Standards offered for citation in the Official Journal, 21.4% are identical or based on ISO standards, while of the 1216 CENELEC standards offered for citation in the Official Journal, 71.4% are identical or based on IEC standards as shown in CEN and CENELEC's Q1/2024 data report.

The Vienna Agreement and the Frankfurt Agreement are the practices that ensure European members continue to have a pioneering role in international standardization. These agreements are effective tools to strengthen European influence internationally and must be well supported within the framework of Regulation 1025/2012.

The participation of European experts following the national delegation principle in international standardization activities supports the inclusion of European priorities in

international standardization. A decoupling from international standardization would neither serve the vital interests of European industries nor the leadership role of the Europe.

## **Inclusiveness of the European Standardization System**

### **Broad involvement**

The standardization system is guided by principles of openness and transparency. Standardization work is open for everyone to participate, and experts participate via their own country and discuss the standards in their own language. As outlined in articles 5, 7, 9 of the Regulation, National Standardization Bodies (NSBs) and National Committees (NCs) promote the participation of relevant stakeholders, including SMEs, social, consumer and environmental organisations to ensure broad participation in standardization committees and to ensure that all voices are heard.

The purpose of the 2022 amendment of 1025 was to ensure that decisions on European standardization deliverables supporting EU policy are made by European stakeholders via the NSBs and NCs of the EU and EEA.

### **Inclusion and increased stakeholder participation**

Inclusion and effective participation are important to develop the best standards that reflect the view of all stakeholders. It is important to lower entry barriers throughout the value chain and make it as easy as possible to participate in standardization work. Among the barriers identified by SMEs is a lack of knowledge about standardization, its processes, and opportunities to participate. There is also a lack of resources, time, and a lack of understanding on the long-term benefits of participating in standardization.

Through Regulation 1025 articles 15, 16, 17, the European Commission can support a wide range of societal actors. To better involve Annex III organisations at national level, initiatives across member states could be harmonized. In addition, European organisations such as ANEC, ETUC, ECOS and SBS can support their national counterparts in becoming more organised nationally and increase their active participation.

Eligible stakeholders can join the High-Level Forum on Standardization and contribute to the debate on European standardization priorities. It is also a space for dialogue between the EC, ESOs/NSB/NCs, member states' administrations, trade and industry associations, academia, standardization experts and various stakeholders.

### **Fundamental rights**

Standardization is a technical matter that should not cross the line into legislation, and it is not the role of standards to set the framework for something that concerns fundamental rights. Therefore, it is important that there is no delegation of legislative or regulatory questions to ESOs in development of harmonized standards.

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## Support of European Policy Goals and Policy Coherence

### Policy Areas supported by the European Standardization System

Regarding the question "*Can you identify any new policy area where the ESS should improve its presence?*", CEN and CENELEC are already involved in developing standards for many topics mentioned in the questionnaire. CEN and CENELEC has technical committees in the following areas: artificial intelligence, quantum computing, blockchain, biotechnology, renewable energy technologies, smart cities, digital health, circular economy and robotics. CEN and CENELEC also develop deliverables that support other topics listed, like sustainable manufacturing, autonomous vehicles, etc.

The decision to develop standards in support of a technical topic is based on the decision of CEN and CENELEC members, in consultation with their stakeholders and considering market need, or through a standardization request issued by the European Commission. These actors evaluate whether CEN and CENELEC should be involved in any topic area. Proposals for new priorities are reported in the Annual Union Work Programme on Standardization, based on the feedback of the High-Level Forum on Standardization.

### Barriers for entering new technical areas

The primacy of international standards does not play a role in the decision to develop standards in new technical areas. Primacy of international standards is a key principle of the European Standardization System, as using international standards when suitable is an efficient way of carrying out standardization work and a way to facilitate international trade. If CEN and/or CENELEC choose to develop standards, both organizations will first see if there are relevant international standards or if ISO and IEC are interested in developing standards in that topic area. If so, CEN and CENELEC will aim to collaborate with ISO and IEC if suitable. If not, CEN and CENELEC will develop a homegrown European standard. These considerations do not impact whether a standard is developed.

## **Annex 1: Position Paper of the CEN and CENELEC Industry Advisory Forum<sup>1</sup> to the Evaluation of Regulation 1025/2012**

### **Re-balance the Public Private Partnership to ensure timely delivery of standards**

The importance of standards in generating revenue and economic growth for society and the private sector cannot be emphasised enough. In a world where globalisation has been an essential driver of economic growth for more than two decades, they frame and guide the development of products and services. As the global and technological landscapes evolve, our European companies' competitiveness and ability to establish new ecosystems will be primarily determined by the general business climate, technology-neutral regulation, and swift development and use of standards. The timely availability of internationally aligned standards will continue to depend on an efficient and trustworthy standardization system.

For the system to be effective, it is vital that all potential standards development are consolidated under the unified governance of the European Standardization Organisations. Such an approach is not only effective in limiting or prohibiting development through non-recognised standardization setters but also ensures a streamlined process.

While Regulation (EU) No 1025/2012 is still relevant and fit for purpose, its implementation could be improved. Specifically, there are issues with the timely development and provisioning of standardization requests, the efficiency of control loops during standards development, the flexibility in transition periods, and the time required for publication in the Official Journal of the European Union. These issues have led to increased administrative overhead and a need for more clarity, resulting in a slow and inconsistent process. To overcome the current situation, a review of the implementation should focus on restoring trust and simplification rather than changing the Regulation itself.

### **Stakeholder involvement**

The Regulation has encouraged the European Standardization Organisations to review their governance models to ensure they address the EU democratic values such as inclusiveness and transparency. Acknowledging that standardization matters for innovation, the active engagement of stakeholders, especially from industry, including small and medium-sized enterprises (SMEs), societal stakeholders, National Standardization Organisations, and governments, is not just encouraged but crucial. The involvement of all stakeholders and the possibility of commenting during the drafting of the Standardization Request are both relevant and vital. To remain efficient, one should identify the roles, committees, and decision-making bodies where their involvement is essential, where they can have real impact, and where they can generate added value.

### **Beyond implementation - Suggestions for improvements to the Regulation**

#### **Formal objections**

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<sup>1</sup>The IAF was established in 2018 as an independent advisory body to provide a platform for a direct dialogue on standardization between CEN and CENELEC and industry

Harmonized European standards are vital for the well-functioning European Single Market, serving users such as industry and market surveillance with an efficient and nonbureaucratic means to ensure compliance with EU legislation. Particularly market surveillance authorities of smaller Member States and SMEs, can be challenged by checking the conformity to European rules when faced with products that lack valid harmonized European standards as the effort required increases drastically in their absence.

Formal Objections against harmonized European standards, as defined in Article 11 of the Regulation, are an essential tool outside of the regular standardization system and are used as a last resort when significant gaps in requirements are identified. However, the system as we know it today has room for improvement. The current system for processing such objections needs improved transparency, and the consideration of the very technical requirements can challenge the high-level experts in the sectoral committees set up by the corresponding Union harmonisation legislation. Creating space for more structured technical discussions of the subject matter can contribute to a more efficient and accurate decision-making process in considering Formal Objections.

An opportunity for fostering this kind of dialogue would be to scrutinise these Formal Objections at the level of the technical experts in the responsible European Standardization Organisation and the authorities behind the objection before further consideration in the relevant sectoral committees through changes in Article 11 of the Regulation. Insights gained from such dialogues can accelerate the process and reduce the time and resources needed from all sides of the downstream stages.

#### Article 11

##### **Formal Objections to harmonized standards**

1. When a Member State or the European Parliament considers that a harmonized standard does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation, it shall inform the Commission thereof with a detailed explanation. ~~And the~~ The Commission shall without undue delay organise a consultation between the European standardization organisations concerned and with the Member State or the European Parliament raising the objection. The conclusion of this consultation shall be transmitted to the committee set up by the corresponding Union harmonisation legislation.
2. After the consultation referred to in paragraph 1 and after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or after other forms of consultation of sectoral experts, the Commission shall decide:
  - (a) to publish, not to publish or to publish with restriction the references to the harmonized standard concerned in the *Official Journal of the European Union*;
  - (b) to maintain, to maintain with restriction or to withdraw the references to the harmonized standard concerned in or from the *Official Journal of the European Union*.
- [...]
4. ~~3-~~ The Commission shall inform the European standardization organisation concerned of the decision referred to in paragraph ~~2~~ 1 and, if necessary, request the revision of the harmonized standards concerned according to Article 10.

Measures to mitigate the need for Formal Objections to be submitted could also be taken. Article 7 of the Regulation already encourages communication between public authorities and the relevant Technical Committees, and the language could be further strengthened recognising that this participation is critical to a well-functioning standardization system in Europe. Such involvement can prevent the need for Formal Objections by broadening the viewpoints involved in standards development and simultaneously increase legal certainty for industry users of harmonized European standards. It would also speed up the process by allowing for direct feedback and exchange rather than depending on interpreting the

objections. Furthermore, the Member States should encourage public authorities to reach out to the responsible national standardization organisation early on for a technical dialogue before submission of a Formal Objection to the European Commission.

#### Article 7

##### **Participation of public authorities in European standardization**

Member States shall, ~~where appropriate~~, encourage participation of public authorities, including market surveillance authorities, in national standardization activities aimed at the development or revision of standards requested by the Commission in accordance with Article 10.

In particular, when Member States consider notifications according to Article 11 (1) for submission to the European Commission, the respective public authorities which consider that a harmonized standard does not entirely satisfy the requirements which it aims to cover, shall be encouraged to enter into a dialogue with the respective national standardization organisation(s) in order to further substantiate the concerns before submission of the notification according to Article 11 (1).

*Proposal to amend Art. 7 of Regulation (EU) 1025/2012*

## Transition Periods

The current system of using a standard period of 18 months for transitions to updated standards sometimes leads to misalignment between harmonisation to different acts of EU legislation as well as between harmonized European standards and their corresponding international and regional versions. These versions are sometimes not even published in some regions before the end of the European transition period, thereby burdening European industry with market-specific deviations. To support efficient long-term planning for the industry, a procedure that enables a flexible, transparent, and content-based determination of the transition period would improve the credibility of the Regulation. Finally, as necessary, there should be provisions for feedback on these periods from stakeholders, such as the European Standardization Organisations.

#### Article 10

6. Where a harmonized standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonized standard without delay in the *Official Journal of the European Union* or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation. If a harmonized standard is superseded by another harmonized standard, its references shall be withdrawn from the Official Journal of the EU. This withdrawal shall come into effect after a transitional period, the length of which shall be determined by the European Commission, if necessary, after consulting with stakeholders, such as the European standardization organisations concerned with the objective of avoiding disproportionate disruptions of the Single European Market. For harmonized standards covering multiple Union harmonisation acts, the listing and transitional periods shall be aligned where possible.

*Proposal to amend Art. 10 of Regulation (EU) 1025/2012*

## Concluding remarks

Although Regulation (EU) No 1025/2012 and the New Legislative Framework are not perfect, they function to fulfil the given objectives and purpose. Any assessment must carefully



differentiate between the Regulation and its practical implementation into processes and procedures.