



July 2025

ETUC response to the European Commission Call for evidence for an impact assessment - Revision - Regulation 1025/2012 on European standardisation

Executive summary

Regulation (EU) No 1025/2012 on European standardisation establishes a legal framework to ensure that products and services introduced to, or circulating within, the Single Market conform to essential legal requirements, particularly those pertaining to health and safety. This regulatory objective is firmly anchored in the broader public interest, which includes the protection of workers' rights and workplace safety.

Within this framework, the European Trade Union Confederation (ETUC) stresses the imperative of inclusiveness as a foundational principle of the European Standardisation System (ESS). Since the adoption of the Regulation, inclusiveness has been integral to the development of European standards, especially those intended to support Union legislation, by guaranteeing the balanced participation of all relevant stakeholders, such as trade unions. This approach is vital to safeguarding both the quality and legitimacy of the standards.

Looking forward, the ETUC calls for a revision of the regulation to further strengthen this inclusive approach, to ensure that technical standardisation supports not only the needs of industry, but also the broader objectives of social justice, workers' rights, worker protection, and sustainable development.

In response to the European Commission's Call for evidence, the ETUC has identified four key challenges the initiative seeks to address, which are inclusiveness, timely delivery of standards, increased flexibility, and global relevance, and has structured its contribution accordingly.

I. Inclusiveness and balanced stakeholder representation

The ESS, as defined by Regulation (EU) No 1025/2012, delineates a framework wherein the legislator lays down essential requirements, while the development of supporting technical specifications is delegated to private standardisation organisations. Industry holds a predominant role in the system by shaping harmonised standards to reflect prevailing market priorities. The application of such standards confers the significant advantage of a presumption of conformity with Union legislation, thereby facilitating legal compliance and market access.

Crucially, the regulation also recognises the need to involve societal stakeholders¹, including trade unions, particularly when standards have implications for workers' health and safety. This inclusive approach is fundamental to ensuring that both economic and social dimensions are adequately integrated in the standardisation process.

¹ [OJ L 316, 14.11.2012, Regulation \(EU\) No 1025/2012 on European standardisation, article 5.](#)



In this regard, one of the ETUC's key priorities in the ongoing revision is to safeguard and strengthen the effective participation of these societal stakeholders who are often underrepresented. However, formal representation alone is not sufficient to guarantee that all contributing voices can be equally heard. Meaningful engagement requires the availability of adequate financial and technical resources and proactive support from standardisation bodies. This is essential given that societal stakeholders have no commercial or financial interest in participating in standard-setting activities, contrary to industrial/business stakeholders. Trade unions contribute with expertise (especially regarding the practical use of standards) without getting any financial return.

a) Ensuring European competitiveness

The current system, shaped by the national delegation principle, is largely influenced by established actors, many of which are non-European actors. This structural imbalance often results in prioritising foreign interests over the broader European public interest and the Union's strategic policy objectives. In this context, the ETUC believes the ESS must be structured instead to better reflect the diversity and specificities of the European internal market, home to nearly 200 million employed people² and an economy in which SMEs represent 99% of all businesses.

A robust and inclusive ESS where stakeholders that truly underpin the European economy are meaningfully represented in both governance and technical processes, would not only strengthen the EU's competitiveness, but also ensure that European standards are aligned with its values and priorities.

b) Avoiding the repurposing of standardisation

While the aim to strengthen inclusiveness is essential, it must not be used to justify the development of technical standards with social and ethical content that extend beyond the legitimate scope of technical standardisation. To safeguard fundamental rights and democratic legitimacy, standardisation must remain strictly limited to technical matters. Issues touching upon rights protected by laws and international conventions – such as workers' rights - should be addressed through appropriate legislative or policy instruments, not through harmonised standards.

Maintaining this distinction ensures that the technical authority of standardisation bodies is not misapplied to areas requiring democratic oversight and legal guarantees. This is particularly important when it comes to matters such as collective bargaining and the autonomy of social partners, which rely on negotiated processes grounded in law and social dialogue, rather than on technical specification.

Proposed actions:

- Continued support for societal stakeholders

Given that *“standards can have a broad impact on society, in particular on the safety and well-being of citizens, the efficiency of networks, the environment, workers' safety and working*

² [Employment - annual statistics - Statistics Explained - Eurostat](#), [page visited on 1 July 2025]



*conditions, accessibility and other public policy fields*³, the Regulation should explicitly guarantee the continued financial support for the effective participation of societal stakeholders.

- Reference to trade unions

Given the specific role of trade unions in representing workers' rights and interests, particularly in relation to health, safety, and working conditions⁴, the Regulation should include a clear reference to trade unions as essential societal stakeholders.

- Facilitating participation at national level

The Regulation only foresees the participation of societal stakeholders in the standardisation activities of the European Standardisation Organisations (ESOs)⁵. The Regulation should, building on its Article 6, further call on National Standards Bodies (NSBs) to encourage and facilitate the participation of trade unions in national mirror committees and to report on the NSB actions to encourage and facilitate inclusiveness in their mirror committees.

- Preserving the scope of standardisation

The Regulation, in line with Recital 12, must clearly delineate the limits of standardisation. Standards must not encroach upon areas governed by EU legislation or collective bargaining, particularly those concerning workers' rights and public services.

II. Timely delivery of standards

The ETUC supports in principle the objective of accelerating and simplifying the standard-setting processes and fully recognises that the timely preparation of standards is necessary for the effective functioning of the internal market. However, the pursuit of speed must not come at the expense of consensus building, inclusiveness, or the rigorous verification that standards comply with EU legal requirements. While procedural simplification may help streamline the system, faster delivery must not undermine the deliberative processes that are essential to producing high-quality harmonised standards that meet the needs of EU policies and legislation⁶.

The evaluation study of Regulation 1025/2012⁷ identified several key challenges contributing to delays in the development of harmonised standards. These include:

1. prolonged negotiations, revisions, and requests for extensions of standardisation requests,
2. consensus building, resource limitations and technical knowledge gaps, and
3. quality control issues in compliance assessments.

Although the ESOs have extensive experience in developing standards and are committed to preparing harmonised standards supporting European legislation and policies, they rely

³ [OJ L 316, 14.11.2012, Recital 22.](#)

⁴ [OJ L 316, 14.11.2012, Recital 17.](#)

⁵ [OJ L 316, 14.11.2012, Article 5.](#)

⁶ [Commission staff working document, Evaluation of Regulation \(EU\) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, SWD\(2025\) 171 final, p. 26.](#)

⁷ [Evaluation Study of the Regulation \(EU\) No 1025/2012 on European standardisation, Section 3.1.4.3](#)



entirely on their members, the NSBs, for timely delivery. In practice, it is often the process of reaching consensus among these actors causes delays.

Moreover, the low rate of positive assessments of harmonised standards, 'with 68.7% of standards receiving a negative assessment by HAS consultants between 2018 and 2022, either for formal or substantive reasons⁸', raises two critical concerns. First, it underscores the need for robust checks and balances to ensure full compliance with Union law. Second, it highlights the need to foresee possible alternatives. The latter will be developed in the following section.

Proposed actions:

- The ETUC calls for a clearer definition of the European Commission's responsibilities under Regulation (EU) No 1025/2012, particularly with regard to its role in the assessment and approval of harmonised standards.
- While HAS Consultants play a critical role in assessing the compliance of draft standards with EU legal requirements, the system has faced persistent challenges. The current HAS Consultant system should be strengthened to meet the demands of all stakeholders in the ESS.
- While procedural simplification is necessary, it must be accompanied by sufficient secretariat capacity both at national and European levels to manage the process adequately and to serve as a true competence centre.

III. A more flexible standardisation system

a) Regular review of the list of European Standardisation Organisations

To address the structural limitations of the current system, the Regulation should be amended to allow bodies beyond CEN, CENELEC, and ETSI to develop standards eligible for harmonisation. At present, only the standards produced by these three ESOs⁹ are considered for harmonisation, on the basis that they adhere to the WTO's founding principles¹⁰. While this has ensured procedural coherence, it has also resulted in a de facto monopoly that restricts institutional flexibility.

Furthermore, following a recent ruling by the European Court of Justice, harmonised standards, as they form part of EU law, must be freely accessible to the public. While national standardisation bodies have agreed to provide read-only access to harmonised standards, international standardisation organisations such as ISO and IEC have not. Given that a substantial proportion of harmonised standards are based on international standards, this divergence threatens to disrupt the system and could significantly hinder the availability of future harmonised standards.

Opening the system to other qualified standardisation bodies that may be able to deliver standards faster, would introduce a potentially more competitive, inclusive, and transparent

⁸ Ibidem, p.27.

⁹ [OJ L 316, 14.11.2012, Article 2, Annex I.](#)

¹⁰ [OJ L 316, 14.11.2012, recitals 2 and 31.](#)



approach. Standardisation requests could be awarded to organisations with the necessary technical expertise, provided they meet clearly defined conditions, such as ensuring inclusive participation from a broad range of stakeholders, including trade unions.

The European Commission would gain the flexibility to mandate other well-positioned and technically competent organisations to develop specific standards where appropriate. This would allow to move beyond the limitations of the national delegation principle, and, by commissioning the development of standards directly, the Commission would retain copyrights over the standards.

b) Common Specifications

Recent adopted NLF regulations – like machinery, AI, and Medical Devices - foresee the possibility to use Common Specifications, as a potential alternative to European standards developed by CEN-CENELEC-ETSI. The revision of regulation 1025/2012 provides an opportunity to introduce Common Specifications by setting out the conditions, procedures, and governance mechanisms for their elaboration and adoption.

Proposed actions:

- The ETUC stresses that common specifications should be used as a fallback option, when the standardisation bodies are unable to deliver the required standards.
- Common Specifications must include clear provisions for the participation of all relevant stakeholders - including trade unions - to ensure that societal and fundamental rights considerations are addressed.
- If bodies beyond CEN, CENELEC, and ETSI are eligible to develop standards for harmonisation, then these bodies must **guarantee** an effective participation of societal stakeholders (including trade unions), in both their governance structure and in the drafting process of these standards.

IV. Strengthen EU's role as global standard-setter

Harmonised standards are a key instrument for implementing the European Union's regulatory and policy frameworks, particularly in advancing its social, environmental, and industrial goals. At the same time, the EU increasingly seeks to position itself as a global leader in standardisation, recognising that influence over international standards is critical to maintaining economic competitiveness and strategic autonomy.

However, these two objectives—internal policy coherence and external influence—can be difficult to reconcile. International standards often reflect the lowest common denominator among diverse stakeholders, which can result in compromises that fall short of the EU's more ambitious regulatory aims. This dynamic creates a structural tension: while alignment with global standards facilitates market access, it may also dilute the normative ambition underpinning the Union's internal policies. Conversely, prioritising high European standards may reduce the EU's ability to shape global standard-setting agendas.



Proposed action:

- The ETUC underlines that the Single Market remains the European Union's most reliable safeguard in an increasingly uncertain global environment¹¹. To maintain its relevance and strength, it must be both protected and reinforced. Rather than preserving the status quo, the EU should adopt a more strategic, inclusive and forward-looking approach to standardisation. This involves actively promoting the participation of European stakeholders, many of whom are currently underrepresented in the standardisation system. Ultimately, the EU's path to becoming a global standard-setter lies in the development of strong, future-oriented standards that reflect societal needs.

In conclusion, if the revision of Regulation 1025/2012 aims to strengthen the EU's role as a global standard setter, it must also reinforce the very elements that have made the European standardisation system a model over recent years: inclusiveness, balanced representation, and the coherent alignment between EU law and European standards.

ENDS.

¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, [*The Single Market: Our European insurance in today's world. Strategy for a Single, Simple and Seamless Market*](#), adoption expected on 21 May.