



September 28, 2023

RE: Comments in Response to the European Commission's Call for Evidence

The American National Standards Institute (ANSI) welcomes the opportunity to provide input to inform the European Commission's Call for Evidence to support its review and evaluation of Regulation 1025/2012, which sets out the rules for the EU's standardization policy.

To begin, ANSI welcomes further information in terms of the perceived need to amend the Regulation at this time. [We understand that the Regulation was recently amended and this revision went into effect in July of 2023.](#) We would very much appreciate any insights you can share in terms of the need to make further revisions at this time, which this [related call for evidence](#) appears to contemplate.

ANSI highlights that the [Regulation points to the need for European standardization activities to \(a\) adhere to the WTO principles that seek to ensure that such efforts are inclusive, open, transparent, consensus-based, etc. and \(b\) coordinate with international standardization bodies \(including but not limited to ISO, IEC and the ITU\). We are interested in further understanding how these requirements will demonstrably be fulfilled.](#)

Today, innovation in emerging and critical technology areas is happening at a rapid pace. To keep pace and address the myriad of needs of these technological areas, the number of standards activities and venues has grown noticeably in the past decade, and the volume of work is expanding in formal consensus bodies, treaty-based organizations, consortia, and fora. Also, a larger number of global players in both government and private sectors are actively engaged in standards processes.

As competition among governments for technology-driven advantages intensifies—and economic, security, and public health challenges continue to raise the stakes at home and around the globe—the need to develop globally accepted standards are growing. An open, rules-based standards system that adheres to recognized due process-based safeguards (including transparency, openness, impartiality, consensus, effectiveness, relevance, and coherence) is key to enabling worldwide participation of stakeholders and facilitating an innovative environment that reflects changing needs in the global marketplace. This marketplace has evolved significantly since 2012 and is expected to continue to change.

The European Standardization System (ESS) and the framework established by Regulation 1025/2012 was developed in a different technological and geo-political environment than what is outlined above. The Regulation presents a structured approach to standardization that does not fully account for the current global standards environment. While Regulation 1025/2012 has been updated periodically since its adoption, the Commission's interpretation of articles

10(5) and 10(6) of the Regulation (following the decision of the Court of Justice of the EU in the James Elliott Court case) has materially undermined the system in recent years.

The EU's approach to Regulation 1025/2012 lacks the necessary flexibility to address urgent needs in rapidly evolving technology areas and has the potential to lead to fragmentation or duplication between (a) European standards and specifications and (b) global standards and specifications. There is evidence that increasing demand for standards in support of EU legislation and policy, particularly in emerging and critical technology areas, has created bottlenecks specific to requested standards and has the potential to overwhelm one or more of the European Standards Organizations (ESOs) and their members, which themselves face EU policy constraints.

The legal framework allowing the European Commission to request one or several European standardization organizations to draft a European standard (or European standardization deliverable) to support EU policy objectives has the effect of prioritizing ENs/hENs as the primary solution to meet regulatory needs. This and the fact that EC regulations do not permit the use of specifications as a suitable tool for meeting European regulations can result in bypassing international standards solutions, particularly those developed by globally recognized, non-traditional standards organizations including those developed by organizations meeting World Trade Organization (WTO) principles. Therefore, this may be a move away from accepted international standards. Restricting input from key and diverse stakeholders can (a) negatively impact the EU standards' global effectiveness, particularly by hindering innovation, (b) constrain global value chain integration, (c) create a bottleneck that could increase compliance costs, (d) perceive this as a barrier that could result in a retaliatory stance in other regions.

In order to anticipate and address current and future standardization needs in today's global economy, the ESS should better coordinate with organizations contributing to the development of all sets of global standards demanded by complex value chains if shared global challenges are to be addressed in effective and timely ways.

Regulation 1025/2012 and the associated 2022 European Standardization Strategy effectively tilts the scale further in favor of the European Commission's direction and away from the private sector. This approach does not seem likely to promote and leverage innovation and can thus be counterproductive. There is concern regarding the potential exclusion of non-EU headquartered companies in regional standards development, particularly in areas where standards work moves from CEN/CENELEC to ISO and IEC, or where joint work takes place. This could result in work being held up at the ISO and IEC and/or lead to a lack of sufficient required "due process" safeguards as articulated by the WTO. There is also continuing concern about the role of Harmonized Standards (HAS) consultants in assessing (a) to which extent the documents, or parts thereof, drafted by the European Standardization Organizations comply with European Commission requests and (b) to which extent they address relevant essential or other requirements set by relevant European Union legislation. This restricts the ability of affected ISO and IEC committees to move work forward.

Regulation 1025/2012 considers only ISO, IEC and ITU to be "international standardization bod[ies]". This definition should be expanded to include international standardization

organizations that develop their deliverables according to the WTO TBT principles¹. Broadening this definition would also facilitate normative references to standards other than ISO/IEC/ITU standards in hENs.

Every day, thousands of European experts participate in the development of globally relevant technical solutions that are needed by their companies and organizations to achieve global business objectives of all kinds. These experts devote their time and expertise working with their peers from around the world, within international technical committees of organizations outside the ESS and outside the international standards bodies designated in Regulation 1025/2012. These organizations, thanks to their agile and robust processes and/or focused scope of activities, are great platforms for the development of science based, WTO-compliant international standards, able to keep pace with innovation in emerging areas. Many national regulators and international organizations reference these globally relevant and globally active standards due to their technical quality, market relevance, and their reflection of state-of-the-art industry technology and practices. Often without formal recognition by governments, such standards also support trade in the EU Single Market as well as global competitiveness of European businesses.

A more flexible approach to the recognition of standards developed within these contexts would better equip the ESS and the European institutions in the anticipation of future needs and would help it strike the right balance between speed and quality in the delivery of timely solutions. While shared challenges are demanding urgency, the current lack of flexibility in coordinating and accepting more diverse sets of global standards in Europe is causing additional delays in the approval of the needed technical requirements and is resulting in costlier and more resource-consuming activities to effectively leverage existing technical solutions as well as develop and identify new ones. As stated above, we would then, again, encourage the EU to establish mechanisms allowing for the establishment of systematic coordination with all global standardization bodies, building on and moving beyond the three organizations specified in Regulation 1025/2012.

The flexibility provided under Regulation 1025/2012 for ICT technical standards/specifications should be extended to all standards and specifications. Such an approach could facilitate provision of cross-border services, encourage competition, and promote interoperability and innovation.

We respectfully suggest that European government officials and standardization organizations need to take steps to address (a) bottlenecks associated with perceived gaps in communication between the Commission and the ESOs, (b) the specific role and authority of HAS consultants, and (c) compliance checks that should be addressed where feasible.

Finally, there also may be benefit in further assessing and possibly strengthening the links between standardization and innovation/ research activities. To begin thinking about standards

¹ TBT Committee Decision on International Standards means Annex 2 to Part 1 (Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement)

early in the life cycle of a new product or technology could be crucial to ensuring a clear, effective, and efficient path to marketplace innovation. Road-mapping is a crucial element of any effort to create new standards, especially for emerging technologies. The benefits of early attention to this task are manifold. A comprehensive roadmap helps secure buy-in and alignment among experts, researchers, other stakeholders, and the appropriate standards development organizations. A roadmap also helps identify pre-existing standards that might be adaptable to new products and systems as well as discover major gaps in the standards landscape that should be addressed, either through updates to existing standards or creation of new standards.

We look forward to continuing to work collaboratively with the EU and European Standards Organizations to advance our shared interests in innovation, providing assurance to consumers, and opening markets.