ITI Promoting Innovation Worldwide

ITI Response to DG GROW Roadmap on the European Standardisation System

The Information Technology Industry Council (ITI) is the premier global advocate for technology, representing the world's most innovative companies from technology, hardware, software, services, and related industries. ITI's 80 members are headquartered across the EU, Asia, and the United States, and are global leaders in information and communications technology (ICT) standardisation, actively driving work in wide range of international standardisation bodies and consortia.

We welcome the opportunity to respond to DG GROW's Standardisation Strategy Roadmap and appreciate continued opportunities to provide a global ICT industry perspective as the Commission contemplates reform of the European Standardisation System (ESS). ITI strongly supports the Commission's objectives of modernising and consolidating the ESS as a means of supporting a well-functioning Single Market, the competitiveness of industries operating in the EU, and the protection of citizens and the environment.

The ESS, founded upon the *New Legislative Framework* (NLF) and the "New Approach" before it, has played a meaningful role in harmonising product legislation and eliminating technical barriers to trade among the Member States dating back to the 1980s, setting an important example for other markets regarding standardisation policy. However, ITI has observed that certain elements of the NLF, coupled with recent European Court of Justice (ECJ) rulings, have created a shift in European standardisation policy that has, in some cases, encumbered adoption of relevant international standards as harmonised European standards. As the Commission undertakes its review of the ESS, we strongly encourage the EU to assess policies that may inadvertently hinder the development of and reliance on international, industry-driven, voluntary technical standards,[1] including digital services standards and particularly for emerging digital technologies. Similarly, the consolidation of EU strategic interests at the international level will be strengthened if the ESS ensures that European standardisation policy promotes inclusion and broad stakeholder participation.

Building on the EU's experience in the development of an integrative ESS, these policy changes can be undertaken in a manner that furthers intra-EU and international policy compatibility, facilitates European innovation and competitiveness, and enables European policymakers to draw on the broadest range of fit-to-purpose technical standards when considering framework or legislative approaches to new technology. Furthermore, such efforts would align with the EU's outward-facing policies advocating for reliance on international standards and acceptance of international test results, rather than reliance on country or region-unique standards or localised conformity assessment bodies.

[1] *i.e.*, All those developed in accordance with 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) in the Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev.13), as may be revised, issued by the WTO Committee on Technical Barriers to Trade.

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Conversely, policy approaches that contemplate deviation from international standards or base policy on government-driven efforts to develop European regional, rather than truly international, standards – whether for ICT products or for digital services – risk furthering fragmentation in the development of what are inherently global technologies and have the potential to slow their development and deployment across the EU. While it is understood that the ESS should be focused on EU interests, the EU should be careful to avoid the risk of cutting Europe off from global flows and efficiencies.

Ensuring Support for and Reliance on International Standards to Demonstrate Conformance

International, industry-driven standards have for many years informed policymakers' development of interoperable technical regulatory requirements for products, while associated international conformity assessment guidelines have offered industry a clear avenue to demonstrate regulatory compliance and ensure reliable product and services interoperability. International standards that are widely used across markets can generate efficiencies of scale and can speed the development and distribution of new innovations, and provide the basis for beneficial technical regulations that are neither discriminatory nor unnecessarily restrictive.

Major strengths of the ESS have been its reliance on stakeholder-driven standardisation for achieving and demonstrating compliance, strong linkages with international standardisation, and a broad reliance within the NLF on self-assessment, which has over time proven broadly effective in allowing innovative technologies to be brought to the European market quickly and safely. However, recent trends have generated concerns regarding the ability to consistently rely on relevant international standards to demonstrate conformance with existing and emerging regulatory requirements. ITI therefore encourages the EU to revisit elements of its existing policies – including core elements of the *New Legislative Framework* -- that have been interpreted as mandating reliance on harmonised European standards as a primary means of demonstrating compliance with emerging regulatory requirements. We recommend that policymakers ensure that EU policy does not inadvertently prevent or slow industry and regulators alike from relying on international, industry-driven, voluntary technical standards – including services standards – as a means of demonstrating conformance with harmonised regulatory requirements.

In line with this recommendation, we encourage the Commission to expand on past efforts, such as the Multi-Stakeholder Platform (MSP) on ICT Standardisation in enabling reliance on international standards to demonstrate conformance with harmonised European requirements for new technology. Given the dynamism of global standards development landscape, the Commission should take a broad and flexible view of the diversity of sources from which global and international standards of importance to the EU may emanate.

The ESS and Interpretation of the New Legislative Framework

As noted in the introduction, our review of the ESS centres largely on its foundation in the *New Legislative Framework* (NLF) and harmonised EU product legislation (*i.e.*, "New Approach" legislation). Regulation (EU) No 1025/2012 provides the current legislative foundation for the ESS,

and, alongside corresponding conformity assessment[2] and accreditation[3] legislation, establishes the legal parameters through which the Commission accords a presumption of conformity to harmonized European standards (hENs). Such standards are developed by the European Standardisation Organisations (ESOs; *i.e.*, CEN, CENELEC, and ETSI) at the request of the European Commission, or otherwise at the international level in International Organisation for Standardisation (ISO), International Electrotechnical Commission (IEC), and/or the ISO/IEC Joint Technical Committee 1 (ISO/IEC JTC 1), leveraging legal arrangements that exist between ISO and CEN and IEC and CENELEC, respectively. Notably, the ESS is rooted in the voluntary nature of standards, and there exists in principle an alternative pathway to compliance in instances where products and services are built/developed to standards other than those to which the Commission has legally accorded a presumption of conformity by its own authority.

However, recent European Court of Justice (ECJ) rulings including the *James Elliot Construction* case (C-613/14) have prompted increased European Commission engagement in the oversight of standards development processes and the development of non-standard technical specifications, in many cases to the detriment of the proper functioning of the ESS. In particular, the *James Elliot* case led to the legal conclusion that hENs are a part of EU law, as their publication in the Official Journal of the EU (OJEU) retains the legal effects of giving a product built to such standards a presumption of conformity with basic regulatory requirements and, as a consequence, the ability to be placed on and circulated in the EU internal market. Moreover, in subsequent analysis, legal scholars have noted that while hENs remain voluntary in nature, "in reality, economic operators find it difficult to comply with the essential requirements of New Approach Directives without the use of harmonised standards," and, "[P]rivate standardisation, therefore, can hardly be seen as providing mere voluntary measures, but rather as setting *de facto* binding rules to regulate the internal market."[4]

The voluntary nature of standards – including those to which the Commission ascribes a presumption of conformity with given essential requirements – has been and should remain a cornerstone of the ESS. The broader implications of the policy developments stemming from the *James Elliot* and other relevant rulings are particularly notable given the Commission's reliance on the NLF in support of recent and proposed legislative initiatives governing new technology. Whether or not directly attributable to the developments described above, as discussed in the following sections, industry notes concerns in the emergence of trends including: **1) the deviation from reliance on international and/or European standards** altogether - in and beyond areas of harmonised product regulation - in favour of non-standard or "standard-like" technical solutions, including technical specifications and codes of conduct; and **2) the decreased availability of international and/or European standards** that may be predictably relied on to demonstrate conformance with harmonised essential requirements. In line with these concerns, we have observed that standardisation requests have become too prescriptive and delayed citation is a significant issue.

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[2] Decision No 768/2008/EC

[3] Regulation (EC) No 765/2008

[4] (2017) Colombo, Carlo and Mariolina Eliantonio, "Harmonized technical standards as part of EU law: Juridification with a number of unresolved legitimacy concerns?: Case C-613/14 *James Elliot Construction Limited v. Irish Asphalt Limited,* EU:C:2016:821," *Maastricht Journal of Comparative and European Law*, https://journals.sagepub.com/doi/full/10.1177/1023263X17709753

Reliance on Non-International Standards in Areas of New Technology: Specific Concerns

As the Commission considers modernisation of the ESS, we wish to draw attention to the following, non-exhaustive list of legislation or processes where industry has noted the potential for deviation from the exclusive reliance on harmonized European, much less international, standards:

- Proposed Regulation of Artificial Intelligence. The EU's recent proposal posits the transposition of the NLF to applications of AI deemed to be high-risk. In addition, it creates legal avenues for the development and application of unique technical specifications where it is determined that harmonized European standards do not exist. More specifically, Article 41 grants the Commission powers to adopt common specifications via implementing acts in cases where relevant hENs do not exist or are found to be insufficient for the protection of fundamental rights. Such specifications could be developed outside of the open, transparent, consensus-based standardisation model, which would severely limit the participation of relevant international experts.
- Cybersecurity Act. This legislative act provides a framework for the development of cybersecurity certification schemes that could apply to goods, services, and processes deemed to have a cybersecurity risk profile. Like the proposed AI Act, it is expected to rely largely on the EU's existing legal framework for European standards and EU-based testing bodies. In addition, it has also resulted in the establishment of ENISA-led ad hoc working groups to set criteria for conformity of digital services.
- SWIPO (Switching Cloud Providers and Porting Data). This European Commission-directed multi-stakeholder group is tasked with establishing voluntary codes of conduct as a means of applying the data porting provision of the EU Free Flow of Non-personal Data Regulation. While superficially similar to standards – and bearing the potential to be applied outside of the context of the EU Free Flow of Non-personal Data Regulation - the development of such codes of conduct has not necessarily adhered to the tenets of due process, open participation and other process attributes that are characteristic of international standards development organisations (SDOs). Industry notes that through extensive consultation with the stakeholder community, the SWIPO governance procedures and policies have been improved since the group's inception (*e.g.*, through development of more formalised complaint processes); however, additional stakeholder engagement and improvements are required to ensure that they reflect those of international SDOs.
- Gaia-X. France and Germany have recently initiated a project focused on the development of a trustworthy and sovereign federated cloud brokerage for Europe. Gaia-X has been characterised by participants and stakeholders as a potential clearinghouse for standards, technical specifications, codes of conduct, and certification regimes developed by other organisations, which may then serve as the basis for identifying approved cloud service providers or otherwise informing European procurement specifications as well as other potential requirements. Thus far, some standards experts have noted concerns with Gaia-X governance processes and transparency.

Regulatory reliance on regional standards or a limited subset of international standards in these policy contexts may lead to unnecessary and avoidable regulatory divergence and market fragmentation in the form of new non-tariff barriers to trade and economic costs to businesses, workers, and consumers. The ICT products space is instructive in this regard: over 80 countries have technical regulations for safety, electromagnetic interference, and telecommunications; many base

requirements on national standards that deviate from global norms. Particularly as the EU and other governments seek to apply standards-intensive regulatory mechanisms to digital services, there is a growing potential for global regulatory fragmentation that would have a significant, detrimental impact on trade in and access to digital services, and also limit the ability of European companies, particularly start-ups and small and medium-sized enterprises, to compete in markets outside the EU.

Moreover, to the extent forthcoming procurement, certification, and/or conformity assessment requirements for digital services are not grounded in international standards, there is a risk not only of market fragmentation (*i.e.*, divergent requirements between jurisdictions), but of technical disruption (*i.e.*, impact on the ability of firms to deliver optimal and secure products and services). We therefore urge the European Commission to avoid wherever possible the development of any bespoke (and therefore region-specific) technical specifications where international standards exist and can be referenced in legislation.

Harmonised Standards (HAS) Consultants

ITI members have noted concerns with the established processes of Harmonised Standards (HAS) consultants. We understand the review of harmonised European standards is intended to ensure alignment with corresponding harmonised Essential Requirements; however, the increased legal scrutiny, reflected in part by the intervention of HAS consultants at late stages when significant time and resources have been expended to develop consensus, is having a detrimental impact on the ability of industry to rely on hENs to place products on the Single Market. Inconsistent implementation of these checks on standards, often in a seemingly arbitrary manner, has inadvertently slowed the process of European standards development. In certain cases, it has created inconsistencies between hENs and widely-used international standards. These ongoing challenges are also causing some ISO and IEC technical committees to reconsider their decisions to jointly develop standards with the ESOs. The absence of readily available harmonised standards requires industry to rely on other means to demonstrate compliance with applicable regulatory requirements, thereby undermining the predictability afforded by the NLF and disincentivising industry participation in the development of hENs. Manufacturers must have a high degree of certainty regarding when a standard may be implemented to meet certain regulatory requirements, especially in an international and competitive market. In addition to the broader standardisation policy recommendations above, we therefore encourage the European Commission to review its current policies to ensure that the review of harmonised standards by HAS consultants does not unduly delay their development and publication or create divergences with international standards that could create market access barriers.

Should the European Commission continue to rely on the HAS consultants, we urge it to adequately resource the consultant program to ensure its effectiveness. We also encourage the European Commission to gather feedback from experts engaged in standards development activities where progress in delivering the final work product has been inordinately delayed due to the actions of the HAS consultants.

Leveraging International Efforts and Addressing Potential Capacity Constraints

As application of the ESS and NLF is expanded into areas of new technology, we note additional risks stemming from current limitations of the ESS, both in terms of readily available relevant harmonised standards as well as EU-based testing capacity. To cite one example, industry noted significant compliance challenges resulting from the initial lack of available hENs necessary to demonstrate conformance with the essential requirements of the updated Radio Equipment Directive (RED). As the Commission adopts standards-intensive regulatory approaches in areas where standardisation efforts are relatively more nascent, such as AI, capacity constraints may be exacerbated to the extent that Commission policy does not allow policymakers to draw upon relevant standardisation work taking place in a range of international standards bodies including ISO/IEC, IETF, IEEE, and 3GPP, as well as more sector or application -specific organizations based both within and outside of the EU. **Enabling transparent and predictable reliance on a broadened range of international standards and specifications would increase the availability of relevant standards to support EU policy and regulatory needs as well as facilitate international compatibility and avoid the development of potentially duplicative regional standards.**

Similarly, Decision 768/2008 and the corresponding provisions contained in harmonised legislation require that any third-party conformity assessment be carried out by a Notified Body established under EU law (*i.e.*, located in the territory of an EU Member State). While this requirement derives from the NLF, in technology areas in which reliance on conformity assessment yields a number of technical and practical questions, **we would strongly encourage lawmakers to allow greater flexibility concerning the acceptance of results from accredited non-European testing bodies, including as a means of demonstrating to third countries the importance of avoiding localised testing requirements that are often redundant.** As discussed in greater detail below, there exist proven international schemes that the Commission could leverage to facilitate the acceptance of international test results and even certifications without requiring negotiation and implementation of government-to-government mutual recognition agreements or comparable conformity assessment protocols.

Lastly, the ESS should, where appropriate and feasible, include measures to embrace digital transformation of standards development processes to enable a more collaborative environment that ensures the timeliness of published standards.

International Engagement

The Roadmap considers the development of "a more strategic and coordinated approach to global standards-setting in areas of strategic EU interest, including through Member States, the European Parliament and European stakeholders, and fostering strategic partnerships with like-minded trading partners." We welcome the Commission's efforts to facilitate collaboration with key trading partners, and furthermore strongly encourage investments in research and innovation as well as standards-related education opportunities. However, leadership in international standards setting as contemplated in the Roadmap must also start with technology and digital policy efforts that prioritize international regulatory compatibility alongside harmonisation within the EU Single Market. We therefore strongly urge the EU to avoid any association of standards leadership with government-driven efforts to develop unique European standards, and instead to lead by example in leveraging and developing international standards where necessary to inform policy frameworks and requirements for new technology.

In this spirit, we see a meaningful opportunity for engagement in the context of the recently established EU-U.S. Trade and Technology Council. We encourage the EU to collaborate with the U.S. to establish a commitment to base regulatory and procurement requirements on international, industry-driven, voluntary technical standards – including those for digital services and green procurement. This commitment will be especially important to facilitate forward-looking international regulatory compatibility in areas where governments pursue standards-intensive approaches to new technology and their applications (*e.g.*, artificial intelligence, cybersecurity, data portability, IoT products). Alongside such a commitment, the U.S. and EU could also initiate work to develop new trade disciplines that extend the benefits from development and reliance on international standards and conformity assessment approaches to digital services.

In addition, the consolidation of EU strategic interests at the international level will be strengthened if the ESS ensures that European standardisation processes are inclusive and provide for broad stakeholder participation. This broad participation comes from not only European interests but global experts in standardisation and conformity assessment. Some European institutions (such as ETSI) provide a model in this regard, and derive great value from welcoming participation from all interests, not just Europe-based experts. EU leadership in international standards-setting is enhanced when it represents cutting edge technological ideas and innovations. In order to ensure this representation is at the highest possible level of expertise, input should be sought from all interests, regardless of their nationality.

The ESS could also seek to enhance global outreach and influence through strengthening the participation within international SDOs and considering leadership roles in strategic areas. While leadership positions are not necessarily indicative of influence, they are important avenues to protect the integrity of the international standards system and processes. While incentivising coordination, efficiency, and flexibility in standards is worthwhile, these incentives should not be offered to promote specific proposals.

Finally, building on points regarding conformity assessment above, where conformity assessment is deemed necessary as a component of regulatory approaches to new technologies, the EU has an opportunity – both in its domestic and trade policies – to lead globally in the development of strengthened provisions that counter localised testing requirements and facilitate the acceptance of test results and certifications through reliance on existing international schemes. These include the International Laboratory Accreditation Collaboration (ILAC) Mutual Recognition Arrangement (MRA) and International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA). **Each of these schemes provides for a rigorous peer-review process that ensures confidence in the quality of test results produced by conformity assessment bodies (CABs) and certification bodies accredited by MLA and MRA members.** The IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) CB Scheme is another example of a successful international system for mutual acceptance of test reports and certificates that has yielded global benefits for the ICT industry. Expanding reliance on these would not only facilitate increased trade in regulated areas where testing, certification and other conformity assessment measures are necessary, but would also have positive ramifications for safety, quality, and consistency, both by broadening the range of acceptable, trustworthy results, and allowing regulators and market surveillance authorities to concentrate resources in the most efficient and effective manner possible.

Research and Pre-standardisation Activities

We welcome the Commission's interest in leveraging the benefits of coordinated investment and collaboration in research and pre-standardisation activities. Such efforts could expand upon well-known European initiatives such as Horizon 2020 to foster partnerships with organisations in like-minded countries to facilitate the mutual exchange of research results among technical experts. Building on ITI's broader policy recommendations concerning the recently established EU-U.S. Trade and Technology Council, we would see significant value in the Commission issuing a clear policy statement that it will favourably consider for use standards that include technical content developed through pre-standards collaborative activities between EU and U.S. parties. As the benefits of research and pre-standardisation collaboration to standards truly pay off when that research and collaboration extend well beyond governmental entities (*e.g.*, NIST-ECJRC collaboration), we urge the Commission to include all relevant stakeholders in such activity, including private sector representatives from academia and industry (*e.g.*, the U.S.-EU NanoEHS Communities of Research (CoRs)).

Promoting a Standards-literate Workforce

The ESS should continue to promote and encourage a standards-literate workforce by building standards awareness and competence among various communities. These efforts should entail a targeted approach to standards education both at the political level and at the industry level. Regulators across Commission services and Member State governments should have access to ample information and educational opportunities concerning the strategic value of standards, including as a means to better understand the standards development process and the dynamics of participation by different stakeholders in international standards setting. Building on the work of institutions such as the European Institute of Innovation and Technology (EIT), education, training, and retraining programs should be tailored to relevant audiences, including industry executives, individuals who participate in the development of standards, implementers of standards, university and college students, young and emerging professionals, and other interested parties.