High-Level Forum on European Standardisation

Work stream 5 "Greater civil society and SME inclusion in international standardisation"

Mapping, analysis and recommendations for greater civil society inclusion in standardisation at international level

January 2025

Leader: ECOS

Supporting members: ANEC
CEN
CENELEC
ETSI
ETUC
European DIGITAL SME Alliance
SBS
Ireland
Sweden

Contents

Background and objective

International standards help remove trade barriers and support convergence globally, allowing EU industry and businesses the possibility to establish worldwide partnerships and sell their products or services worldwide.

The European Standardisation System (ESS) and its policy framework recognise the critical role of international standards and hence, international standards are also part of the European standardisation. The EU Standardisation Strategy[1] highlights: "*Europe's competitiveness, technological sovereignty, ability to reduce dependencies and protection of EU values, including our social and environmental ambitions, will depend on how successful European actors are in standardisation at international level.*" The Strategy underlines "*More than ever, standards do not only have to deal with technical components, but also incorporate core EU democratic values and interests, as well as green and social principles.*" The focus on inclusiveness sets the ESS apart and distinguishes it from other standardisation systems.

The success of the ESS rests collaboration from industry experts, public administrations, civil society, research and academia to deliver on the critical aspects of standards development to ensure that European standards meet the needs of various sectors and stakeholders. It is critical to ensure the inclusive and effective participation of civil society and SMEs in national, European, and international standardisation, to guarantee a pool of future experts to achieve a well-functioning standardisation system.

The report is the result of the work of Workstream 5 'Greater inclusiveness of civil society and SMEs in international standardisation'. The workstream was established to support European goals for leadership and ambition in standardisation at international level. Its objectives include preparing an analysis, mapping, and roadmap for increased civil society and SME participation in international standardisation and providing recommendations to enhance the inclusiveness at the international level.

Regulation (EU) No 1025/2012 recognises that European standards are developed by the European standardisation organisations, CEN, CENELEC and ETSI; and as 'international standardisation body' the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU). This report focuses on CEN, CENELEC and ISO and IEC due to the experience of the Annex III organisations. It also proposes an analysis of ICT standardisation in ETSI and ITU-T (see section on recommendations).

The report begins with a mapping of rules for participation in two international standardisation organisations, the ISO and the IEC. The report examines these rules within the European context for participation of under-represented stakeholders, identifies the strengths and weaknesses in supporting participation at international level. The report provides recommendations for improvement taking stock of existing good practices and identifying institutional opportunities.

---

[1] [COM(2022) 31](COM(2022) 31)

The international standardisation context: Mapping and analysis of governing principles & existing rules for participation

Given the increasing relevance of international standards, and the existing interplay between European and international standards, it is important to understand the aspects and implications of participation principles and rules in international standardisation, particularly of European SMEs and civil society organisations.

This analysis collects information about current rules of participation for European civil society and European SMEs at international level and opportunities for improvements.

This section reviews the general principle governing participation in ISO and IEC standard-writing activities. It sheds light on existing technical cooperation agreements between these organisations and their European counterpart, to identify and assess potential provisions regarding the participation of SMEs and civil society organisations.

Figure 1 illustrates the landscape of key principles, actors, and cooperation mechanisms in the interplay between International and European standards.
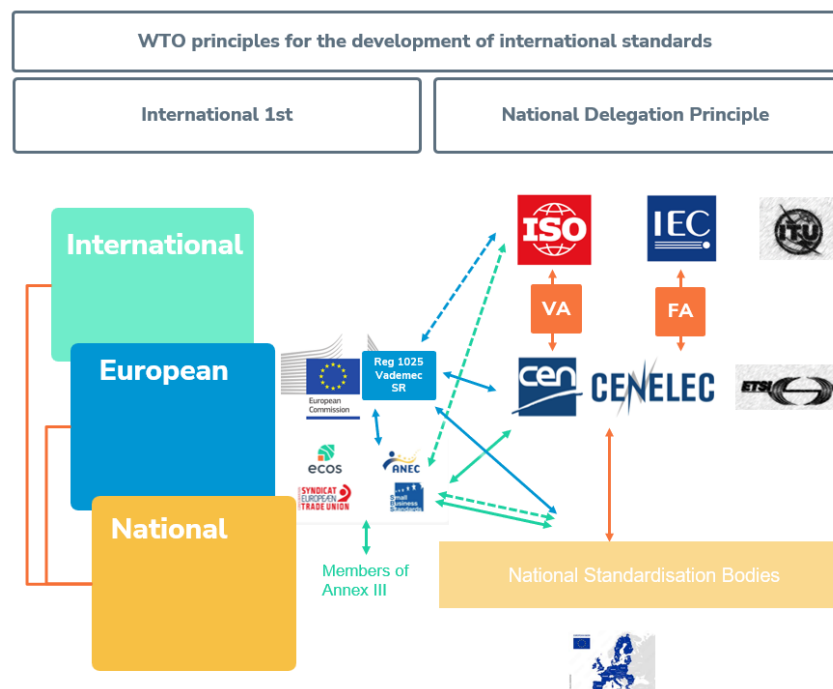

Figure 1: Overview of key actors and cooperation in the interplay between International and European standards.

European Regulatory Framework

In Europe, standardisation is a crucial tool for constructing the Single Market and supports a wide range of policy objectives, including health and safety in the workplace, environmental protection and product safety. Council Resolution 85/C 136/01 established a "New Approach" in European standardisation, focused on removing trade barriers and ensuring high levels of protection. The technical specifications for meeting the essential requirements are laid down in harmonised standards developed by one or more of the European Standardisation Organisation (CEN, CENELEC and ETSI) at the request of the European Commission[2].

The growing use of standards in support of public interest objectives in Europe, has been accompanied by the development of a regulatory framework, including the "New Legislative Framework"[3] (NLF) and the 1025/2012 Regulation on European standardisation. The latter includes provisions to support and improve the inclusiveness of the European Standardisation System (ESS).

Regulation 1025/2012 applies to all standardisation work requested by the EC under a Standardisation Request (SREQ) whether developed within the ESOs or their international counterparts. However, when the standards are drafted within the International Standardisation Organisations, the governance framework and rules differ from those in the ESOs, potentially impacting inclusiveness.

Interplay between European and International Standards

Technical cooperation agreements between ISO and CEN, and between IEC and CENELEC—known as the Vienna Agreement (VA) and the Frankfurt Agreement (FA)—establish modes of collaboration for adopting international standards as European standards[4]. The agreements acknowledge the specific European regulatory framework (and provide the possibility to proceed separately, should the international standard not align with European regulations). Both ISO and IEC are committed to WTO values such as transparency, openness, coherence, impartiality, and relevancy.

The VA provides two modes of cooperation for the simultaneous standard approval, either under "ISO lead" or "CEN Lead". The FA commits to primarily undertaking work at international level and proposes that a European standard be offered to the international level for revision, regardless of its origin. IEC standards to be adopted as European standards, can be adapted for the European market through CENELEC if necessary.

However, since the VA and FA are private agreements, they are not subject to the inclusiveness requirements of Regulation 1025/2012. European technical committees within CEN and CENELEC are the primary tool for ensuring the inclusiveness provisions of Regulation 1025/2012 are applied to work carried out under the FA and VA. European societal stakeholders and SMEs can participate to the work in the European Technical Committees that process ISO/IEC led work making use of the rights and obligations as per their partnership agreements with CEN and CENELEC[5] (national Societal stakeholders and SMEs can also participate to this work through NSBs mirror committees following the National Delegation Principle). This comprises being able to join any CEN and/or CENELEC Technical Body,

---

[2] In order to provide a presumption of conformity with essential requirements established by the Directives, the references of harmonised standards (hEN) must be published in OJEU. The EC can also request the development of hEN (or other standardisation deliverables) that are not intended for publication in the OJEU, thus not providing a presumption of conformity.

[3] The "New Legislative Framework" has been adopted in July 2008 on the basis of: Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93; Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

[4] At that time known as the Lugano Agreement, subsequently amended in 1996 (the Dresden Agreement) and in 2016 (the current Frankfurt Agreement).

[5] CEN-CENELEC Guide 25 The concept of Cooperation with European Organizations and other stakeholders (Updated version, January 2024)

including Technical Committees and Working Groups without having to apply or taking part in CEN and CENELEC Technical Committees as Observers and in Working Groups as Experts with equal rights. However, participation of civil society and SMEs in international work through CEN-CENELEC committees can sometimes have limited influence.

In such cases, European actors – including societal stakeholders and SMEs - must be part of NSBs' mirror committees or coordinate their membership at the national level to participate in the work of CEN-CENELEC committees when processing international work. The High-Level Forum (HLF) workstream #3 on the national peer review concluded that more active participation at the national level would be beneficial, though challenges remain.

For direct participation, non-members of ISO/IEC must apply for liaison organisation status to be actively involved in the standard-development process within technical committees and working groups (*see section Participation in ISO and IEC*). This brings about some limitations as compared to the conditions to participate in CEN/CENELEC- which is applicable equally European societal partners and other organisations (see Section: *Limitations to the participation of EU civil society and SMEs in international standardisation*).

WTO principles & the Primacy of International Standards

Despite careful wording of WTO principles for the development of international standards[6], a wide range of international bodies still have the capacity to define technical specifications. The WTO defines principles[7] for the development, adoption and application of international standards by standardisation organisations. Consequently, a wide range of organisations may claim the ability to set international standards. Over the past decade, however, the EU has promoted the acceptance of ISO, IEC and ITU as international standardisation bodies in trade agreements.

The European framework goes beyond the WTO's openness principle, aiming to achieving balanced representation of stakeholders, by referring to inclusiveness and recognising the need to facilitate effective participation of under-represented stakeholders in the standardisation process.

The "primacy of international standards" is a well-established principle in both international and regional trade agreements, as well as in the European Commission's approach to standardisation. The WTO Agreement on Technical Barriers to Trade (TBT) firmly establishes that international standards, or their relevant parts, must be used as the "basis" for the adoption of technical regulations by WTO members (article 2.4 of TBT).
The European Commission's policy is also aimed at aligning European Standards as much as possible with the international standards adopted by recognised international standardisation organisations, such as the ISO, IEC and ITU. It is preferable that European standards are based on international standards or in some cases international standards are based on European standards. The HLF is discussing this issue under the workstream #4 'Alignment of European and International standardisation'.

---

[6] In fact, six "Principles for the Development of International Standards, Guides and Recommendations" have been agreed upon by the WTO TBT Committee in 2000. These principles are also largely referred to in the 1025/2012 Regulation and are: transparency, openness, impartiality, consensus, efficiency and relevance, coherence, development dimension. See Annex 4 of the "Second triennial review of the operation and implementation of the agreement on technical barriers to trade". Available at:
https://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/TBT/9.doc. See also
https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm., accessed on the 06.10.2023.
[7] For example, within the WTO framework, the openness principle to qualify as an international standardising body requires solely to be "open on a non-discriminatory basis to relevant bodies of at least all WTO Members" See
https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm#:~:text=2.-
,Openness,at%20least%20all%20WTO%20Members., accessed on 6/10/2023.

The primacy of international standards is a key element of the technical cooperation agreement between the CEN and ISO (VA)[8] and between the CENELEC and IEC (FA)[9]. As of June 2023, 34,4% of all CEN's standards originated from ISO publications, and 74,4% of all CENELEC's standards from IEC[10]. Moreover, about 3.400 documents from the CEN-CENELEC portfolio are cited in support of European legislation. Those harmonised European standards represent approximately 13% of all standards adopted in Europe[11]. About 40% of these are identical (or nearly) to ISO or IEC publications[12]. In other words, cited harmonised standards which originate from international standards create approximately 6% of all European standards. These are, however, of a great importance due to their link to legal requirements in European legislation.

It is therefore noteworthy that while the primacy of international standards used in support of European legislation brings opportunities to promote European know-how and values, it also brings specific challenges in the European context with regards to inclusiveness.

Participation in ISO and IEC

Direct participation in ISO and IEC is either as a working group Expert via the National Body or as a liaison organisation. When a European Technical Committee is formed to cooperate in parallel on ISO/IEC led- work, European stakeholders are able to participate in that forum.

National Delegation Principle

The work of ISO or IEC (as well as CEN and CENELEC) follows the "national delegation principle" where a national standardisation body (NSB) or national committee (NC)[13] holds the voting rights and is responsible for conveying the national consensual position on a draft standard.

In Europe, participation in the work of ISO or IEC is open to all interested parties and channelled via NSB/NC 'mirror committees' which reflect the work of the ISO and/or IEC technical committees. NSBs decide on the experts to be nominated and delegated to ISO and/or IEC committees following their internal regulations. Within these mirror committees, national positions are discussed and agreed. If the representation of societal partners and SMEs in the NSBs/NCs is weak (either due to the lack of experts or the lack of inclusiveness at national level), there is a risk that the societal values are not brought to the international level sufficiently.

Companies and organisations nominate experts to participate in the relevant technical bodies of standardisation organisations at the national level. All stakeholders *can* take part in standardisation work. According to ISO data, consumer interests represent less than 1%[14] of all stakeholders recorded involved in technical bodies.

---

[8] Available at: https://boss.cen.eu/media/CEN/ref/vienna_agreement.pdf
[9] Available at: https://www.cencenelec.eu/media/Guides/CLC/13_cenelecguide13.pdf
[10] See CEN-CENELC Global outreach report, June 2023, available at https://www.cencenelec.eu/media/CEN-CENELEC/European%20Standardization/Documents/IC/global_outreach_june2023.pdf , accessed on the 06.10.2023.
[11] CCMC analysis in 2024 based on the publicly available information for 2023 on CEN-CENELEC webpage.
[12] See excerpt from CEN-CENELEC in Figures in Annex 2; in total, about 1300 CEN and CENELEC deliverables offered for citation are identical to ISO or IEC publications. Not all deliverables offered for citation might effectively be cited in the Official Journal of the European Union (OJEU).
[13] 'National Standards Bodies' are the members of ISO while 'National Committees' are the members of IEC. In some European countries, a single organisation covers both memberships.
[14] ISO COPOLCO internal assessment. 2024.

Liaison Organisation Status

The usual way to participate in drafting international standards is through membership in a national standardisation body that is a member of ISO or IEC. However international and regional organisations that are not members but who have the knowledge and willingness to make active contributions can participate as recognised liaisons.

In ISO and IEC, "the work is carried out by experts in the subject drawn directly from the industrial, technical, and business sectors that have identified the need for the standard, and which subsequently put the standard to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations and academia, and by international governmental and nongovernmental organizations"[15].

European civil society and SME associations, intergovernmental entities, and the European Commission fall under the category of 'other experts' and can participate in the ISO and IEC standards development process as "liaison organisations." Eligibility criteria, rights and obligations of the different categories of liaison organisations are provided by the ISO/IEC directives (an overview is provided in Annex 1). The key features of the liaison status within the scope of this assessment are:

- An application to become a liaison organisation must be made on a case-by-case basis, meaning that for each technical committee and/or subcommittee of interest, a new application must be submitted to ISO or IEC.
- The granting of liaison organisation status is subject to vote and approval by the corresponding technical committee and subcommittee;
- The liaison organisation has no voting right but can provide comments on draft standards.

While liaison organisations contribute mainly to the technical work of ISO or IEC, their status can also provide access to policy development committees.

For example, in ISO, the Committee on Consumer Policy (COPOLCO) does not develop standards but serves as a policy forum. Its membership is open to ISO full and correspondent members. Its objectives include identifying priority ISO standards work for consumers, coordinating consumer representatives, improving of consumer participation through publications and training as well as advising the ISO Council on consumers views on matters relevant to ISO's current and potential standardisation and conformity assessment work, and on the need for new or revised policies or actions to address consumers' needs. Such policy development committees play a role in advancing participation of civil society organisations in international standardisation, although the effective participation is through the national delegations.

Discussion: gaps regarding inclusiveness, strengths and weaknesses

The inclusiveness of the international standardisation organisations depends on the implementation of the inclusiveness principles by their members as well as on their governing principles and rules for participation. The key existing principles, mechanisms, and rules for engagement of societal partners and SMEs in international standardisation are not fully on par with the European regulatory framework. These differences can limit the participation of European societal stakeholders and SMEs and should be addressed. This is key to ensure that the conditions under which European Standardisation Requests addressed to the ESOs are passed on at international level are in line with Regulation 1025/2012 Articles 5, 6 and 16.

---

15 ISO. Guidance for ISO liaison organisations. Engaging stakeholders and building consensus. 2010.

Inclusiveness, a clear strength of the ESS

With the entry into force of Regulation 1025/2012, inclusiveness became a central pillar of the European Standardisation System (ESS), recognising the role of societal stakeholders and SMEs. Inclusiveness of the ESS has been further strengthened by measures such as CEN-CENELEC Guide 25[16] that define the role and responsibilities of all partner organisations, and the specifics for the Annex III organisations. The guide enables them to join technical committees and working groups as a right. Specific initiatives like the SME Working Group (SME WG) and the Societal Stakeholders Group (SSG) have been created to address stakeholder concerns more directly.

An important achievement of the SSG has been to develop a right of opinion for societal stakeholders (i.e., currently, ECOS, ANEC and ETUC) and since recently also to SMEs (i.e., currently SBS), providing them with a possibility to cast a formal opinion on a draft standard at enquiry or formal vote stage. Dedicated training materials and publications for civil society organisations and SMEs have been developed and promoted to sustain the inclusiveness of the ESS[17]. Online access to normative documents[18] has been granted to Annex III organisations (nevertheless, this is still not the case for international standards even if adopted as European ones), testifying European commitment and actions to further improve inclusiveness[19].

The London Declaration adopted by ISO members (and endorsed by the IEC, CEN and CENELEC) aims to ensure global standards support climate action, while involving of civil society and those most vulnerable to the effects in the development of all international standards and publications.[20] In this regard, the London Declaration should provide opportunities to improve inclusiveness of the standardisation process at ISO and IEC level – and this can be driven by the European NSBs who operate in the regional system aiming for a more balanced representation.

This is particularly relevant when internationally grown standards will be taken up as European standards to underpin EU legislation as all mandatory provisions in Regulation 1025/2012, also in terms of inclusiveness, need to be met. While European organisations representing societal stakeholders and SMEs have been granted financial support and rights to access relevant technical committees and policy groups within the ESS, the situation is not the same within the international standardisation system where access calls for case-by-case applications and approval procedures at the technical or policy development level. From this perspective, harmonised standards developed at the international level might not reflect the requirements for inclusiveness as defined and implemented in Europe.

Limitations to the participation of EU civil society and SMEs in international standardisation

As mentioned above, participation in ISO and IEC led standards is either (i) participation in the European Technical Committees set up to cooperate with ISO/IEC, (ii) via the National Body, or (iii) as a liaison.

---

[16] https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclcguide25.pdf Updated version, January 2024.
[17] See for instance the dedicated training available at: https://www.standards4all.eu or the CEN-CENELEC publication for civil society, available at: https://www.cencenelec.eu/media/CEN-CENELEC/Get%20Involved/Societal%20Stakeholders/civilsocietyleaflet.pdf , accessed on the 06.10.2023.
[18] A normative reference is "a document to which reference is made in the standard in such a way as to make it indispensable for the application of the standard." Such normative reference frequently implies other standards, see https://boss.cen.eu/reference-material/guidancedoc/pages/normref/, accessed on the 06.10.2023.
[19] See https://www.cencenelec.eu/news-and-events/news/2022/brief-news/2022-12-08-a-new-step-to-strengthen-the-inclusiveness-of-cen-and-cenelec-system/, accessed on the 06.10.2023.
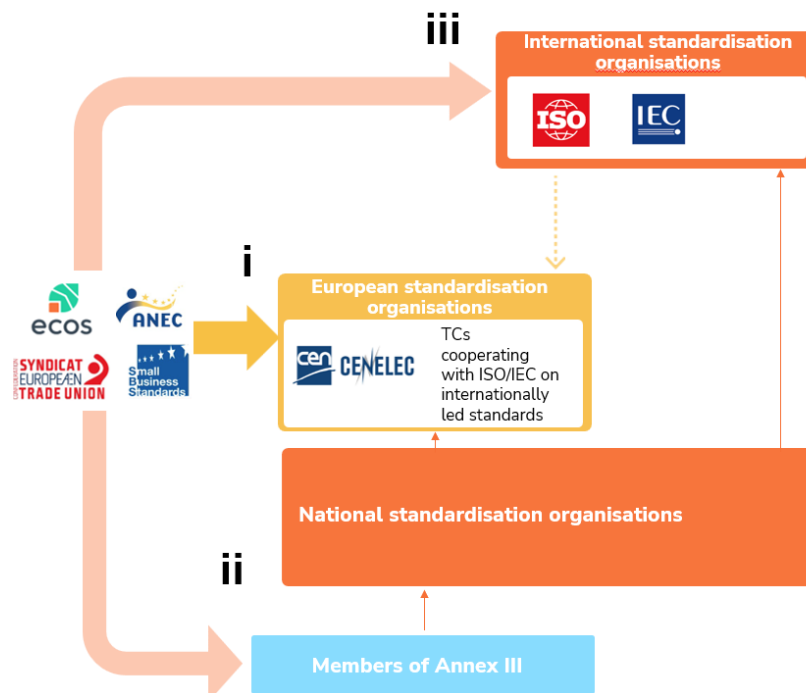[20] See https://www.iso.org/news/ref2726.html , accessed on 9.10.2023.

Figure 2: Annex III organisations face limitations in joining international standardisation either via the national level or directly as liaison organisations.

European civil society and SMEs have faced limitations and see room for improvement:

(i)   In those cases when a European Technical Committee has been set up to cooperate with ISO/IEC work led internationally, European societal stakeholders and SMEs can participate with the rights and obligations as in Regulation 1025/2012. Difficulties observed in such cases are as follows:

   • Most ISO/IEC lead have a European committee mirroring their work. However, in some cases, CEN-CENELEC BT can agree to adopt an international standard directly. This limits the chances to influence the drafting of those international standardisation deliverables.

   • When participating in international work through CEN-CLC committees, Annex III influence is limited as there is already consensus at the international level. Furthermore, in those cases where parallel procedures are run, Annex III organisations can submit comments during the public enquiry, but they will not be able to attend and defend their positions at the comment resolutions meetings in ISO/IEC.

(ii)   One of the most evident strengths of the ESS regarding participation in international standardisation is its reliance on the shared principle of the national delegation. In this view, actions taken at the European level to reinforce participation at NSB or NC level will not only strengthen the ESS but also the position of European NSBs and NCs in international standard-setting activities taking place at ISO or IEC level. As such, the existence of a European regulatory framework for standardisation provides a basis for the development of actions aimed at strengthening European participation at the international level. The corresponding development of dedicated actors, such as the Annex III organisations, networks, policy groups and committees are an additional advantage to support and foster the European impact on international standardisation at ISO and IEC level.

Despite improvements in recent years at European standardisation level and work of many NSB/NCs at national level, there is room for further progress in the participation of societal stakeholders and SMEs in European NSBs. This is confirmed by the work developed by the HLF within the workstream #3 'NSBs peer review, including SMEs and civil society inclusiveness' that has revealed several critical findings that highlight the successes achieved as well as the significant challenges that remain. NSBs in Europe understand the importance of involving all stakeholders in standardisation, including civil society and SMEs, and the need still to make progress. While it has not been possible to compile data on the proportional distribution of stakeholders in TCs at national level for this report, HLF Workstream #3 data show that "Regarding participation of stakeholder representatives in the governing structures and/or advisory bodies, 57% of NSBs include SME and societal stakeholder representatives permanently in such structures, while 27% have no such measures. About 25% create advisory bodies aimed at discussing issues concerning underrepresented stakeholders (similar to the CEN-CENELEC Groups for SMEs or Societal stakeholders) or invite these stakeholders to governing or advisory bodies meetings on an ad-hoc basis.'" Results indicate there is room for improvement also from the rest of the European standardisation stakeholders such as the societal partners and SMEs side and Member States. In this sense, there is still the need for an added push for a more balanced representation at the EU national level to unlock the knock-on effect in the European and international standardisation levels.

Furthermore, identification and engagement of societal stakeholders and SMEs at national level needs also to be reinforced. All this points to a gap in inclusiveness for national organisations representing the interests of societal stakeholders and the good functioning of the ESS based on the national delegation principle, from where NSBs and NCs organise and channel participation in European and international standardisation work. This aspect is being explored in workstream #3 of HLF.

(iii)   When European standards are developed at the international level and Annex III organisations want to directly participate, they can only join as liaison organisations (an overview is provided in Annex 3) with access conditions inferior to the levels prevailing in Europe to implement Regulation 1025/2012:

- In contrast to the European framework where the Annex III organisations are able to join a CEN-CENELEC TC and WG as of right (based on the Regulation 1025), in international TCs they are not guaranteed the participation automatically. Liaison organisation applications are considered on a case-by-case basis, and decisions are taken by a committee's national members. Eligibility criteria are an additional burden for a candidate liaison organisation. More importantly, a possible rejection of a liaison request leads to the exclusion the applicant. ECOS, ETUC, and SBS have had their requests for liaison status rejected by some ISO and IEC Technical Committees (TCs), preventing them from contributing at the international level. To avoid this, a more proactive support from European NSBs/NCs (i.e., positive vote instead of abstentions) in the liaison vote could increase the chances of acceptance.
- Lengthy process for the adoption of a liaison request. The timeline for handling the application is not specified in the ISO/IEC Directives. There is no set deadline from the application until the request is circulated to the TC members for vote. Often this entails significant delays in the application process to the point of the liaison vote being unjustifiably postponed and (risking) key commenting milestones being missed.
- Costly participation in international work. The standardisation systems heavily rely on the contribution of technical experts that are working for companies/corporations who agree to pay for the hours they spend in standardisation activities and related costs. These costs are mainly an investment because they allow the companies/corporations

to participate in the development of technical references that are key to their success in the market and help them remain competitive. By comparison, societal stakeholders (e.g., consumers, trade unions, environmental stakeholders) and non-profit organisations do not recuperate their investment in standardisation work (as they do not sell products/services); therefore, only with specific funding, can they participate. Lacking financial and personal resources might lead to lower representation of the European societal stakeholders in international standardisation. This is made even more acute when international standardisation meetings can be held across the globe and the financial support is insufficient.

- Annex III organisations have special rights for participation on hENs development in the European framework. At the international level where they do not have this special recognition, they must follow the ISO/IEC rules for participation, as other societal partners. This hinders their influence when contributing to the drafting of the international standards. The lack of right of Opinion, for instance, means that under-represented stakeholders do not have a mechanism to flag their support or not for an international standard under vote, a view that may well be missing from the national level. Similarly, only consumers have a dedicated group for bilateral engagement with the governing bodies of the international organisations, ISO COPOLCO.

The need to get the interplay between European and international standards right

Especially in the current context of an overall lack of technical expertise, and the development of new standardisation areas at global level, proactive engagement of consumer, environment, trade union and SME representatives is of paramount importance for international standards-making too.

The conditions under which harmonised standards, developed in response to Commission Standardisation Requests approved by the ESOs are developed under the lead of ISO or IEC are established in the Vienna and Frankfurt Agreements, and the CEN and CENELEC Internal Regulations Part 2 provide some main criteria. Nevertheless, the ways to ensure balanced participation are undocumented and unclear and should be defined. The revisions[21] of the *guidelines* for implementation of the VA and the annual update to the IR Part 2, could be an opportunity for this.
The Vademecum on European standardisation is silent on this point. Regulation 1025/2012 always applies to work done in execution of Standardisation Requests regardless of where the standards are rooted. However, some provisions of Regulation 1025/2012 such as those on inclusiveness could be more difficult to apply if the standard-setting process takes place at the international level as argued above. Overall, the implementation of the Regulation could be seen as inconsistent to achieve inclusiveness; for NSBs in terms of societal stakeholders (SMEs are covered by Art 6); and for Member States in terms of financial support to national organisations representing the interests of all societal stakeholders.

Moreover, as underlined by Eliantonio and Volpato, neither Regulation 1025/2012 nor the contractual relationship between the EC and an ESO (in the form of the execution of the Standardisation Request) sets the conditions under which the decision to "outsource" the standards-development process to the international level can be taken[22]. The Vademecum, which provides guidance on the adoption and

---

[21] "Revision of the guidelines for implementation of VA occur upon the need. The revision of IR Part 2 occurs usually once a year, maximum once in two years." Information from CEN-CENELEC, 2024.
[22] See Eliantonio, M. and Volpato, Annalisa, The European System of Harmonised Standards. Legal Opinion for ECOS (March 11, 2022). Available at SSRN: https://ssrn.com/abstract=4055292 or http://dx.doi.org/10.2139/ssrn.4055292, p. 36

execution of standardisation request[23], also remains silent about the processes underpinning the transfer of the standards development work to the international level. As such, who is deciding what, when and how remains to be clarified in cases where European standards with a legal nature are developed at the international level.

With the different access conditions at international and European level, adherence to the principle of primacy of international standards by European civil society organisations and SMEs could be at risk being undermined. It is therefore important to work towards ensuring greater inclusiveness at international level. This is especially crucial given the importance of inclusiveness in the European Standardisation System (ESS), which aims to involve all relevant stakeholders in the standard-setting process.

In the next section, we propose a set of recommendations to better equip the ESS and its stakeholders in terms of inclusiveness and balanced participation for international work.

Recommendations for greater civil society and SME inclusion in standardisation at international level

Drawing on the insights above after a series of iterations among the workstream members and other interested HLF members and to foster greater civil society and SME inclusion in standardisation at international level, the following recommendations are proposed as actions to be taken forward by the European standardisation stakeholders:

1. Foster greater inclusiveness at national level for the knock-on effect on international

2. Annex III organisations have their effective participation facilitated at the international level

3. Develop policy rules and guidance for harmonised European standards being passed to international level for development

4. Promotion of inclusiveness measures in the ESS and the role of Annex III organisations as best practice for international standards making

5. Conduct a specific analysis on inclusiveness and participation for the particular case of ICT standardisation in international standardisation bodies

Adequate implementation and setting up of a monitoring system to track progress of the actions and measure their effectiveness will be key.

Recommendation 1: Foster greater inclusiveness at national level for the knock-on effect on international

---

[23] The three-part Vademecum provides guidance without having legal status, it compiles key documents from the EC on standardisation policy and related practice. See: https://single-market-economy.ec.europa.eu/single-market/european-standards/vademecum-european-standardisation_en#:~:text=This%20Vademecum%20compiles%20key%20documents,guidance%20without%20having%20legal%20status. Accessed on 09/10/2023.

NSBs and NCs form the backbone of the ESS and ISO/IEC participation model. Greater inclusiveness by European NSBs/NCs will simultaneously reinforce effective participation of civil society and SMEs at European level and at ISO/IEC level. At the same time, Member States and the public authorities play a central role in reinforcing the national standardisation structures and committing to strengthen participation.

Considering the work undertaken as part of the HLF workstream #3 "NSBs peer review, including SMEs & civil society inclusiveness" and in view of alignment and efficiency of the work within the HLF, the specific actions to foster civil society and SME participation within European NSBs and NCs is included as part of its work. National standardisation stakeholders have participated in the activities under the HLF workstream #3 which renders it a more adequate platform.

The proposals, stemming from the HLF workstream #5 work, were brought forward for consideration and possible adoption as actions under HLF workstream #3:

EU MEMBER STATES AND PUBLIC AUTHORITIES:
o Put in place national funding schemes to directly support civil society organisations and SME representation and participation at national level, in order to lead into European and international standard-setting activities.
o Organise awareness-raising activities about standardisation, including solutions implemented at national level that foster inclusiveness. A special focus on the role of national mirror committees active in international standardisation work should be considered.

NSBS AND NCS:
o Encourage and facilitate appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations, environmental and social interests in their standardisation activities.
o Further implement favourable access conditions based on best practices identified across Europe for participation in the national committees mirroring international standardisation work.
o Encourage and facilitate appropriate representation at technical level of research centres, universities and public authorities, in standardisation activities concerning an emerging area with significant policy or technical innovation implications.
o Report yearly on compliance with the provision in Art. 6(2) of Reg. 1025/2012 to exchange best practices among themselves.

CEN AND CENELEC AND EU ORGANISATIONS REPRESENTING SMES, CONSUMERS, ENVIRONMENTAL AND SOCIAL INTERESTS:
o Improve data collection regarding participation of different stakeholders through CEN-CENELEC Membership Relations and Monitoring Committee (MRMC) and internal membership assessments to better inform any decisions.
o Contribute to the revision of the CEN-CLC questionnaires to NSBs/NCs for the annual exercise of the report to Regulation 1025/2012, in particular regarding the mapping of national SSOs and national SMEs organisations involved at national level - with the aim for NSBs to share and implement best practices on balanced representation of the SSOs and SMEs organizations involved at the national level.
o Identify NSB national contact points & Annex III national constituencies for cooperation.

EU ORGANISATIONS REPRESENTING SMES, CONSUMERS, ENVIRONMENTAL AND SOCIAL INTERESTS:
o Continue to directly cooperate with NSBs and NCs in the form of co-organised events to raise awareness on the importance of proactively reaching out to such stakeholders to contribute to standardisation at national level.

o Continue to coordinate their national members to strengthen participation via the national delegations.

o Evaluate the possibility for funding under Regulation 1025/2012 for training materials on social inclusiveness for NSBs/NCs, TC experts and consider other best practices.

Recommendation 2: Annex III organisations have their effective participation facilitated at the international level

This would be for standards aimed at supporting European legislation.

CEN AND CENELEC:
o to set up a mechanism for the access of Annex III organisations to the information on who is going to be assigned the work under a Standardisation Request with accent on international organisations. That will help the Annex III organisations better anticipate if they need to request a technical liaison in the related international TC/SC at ISO/IEC.
o to inform their members about the intention of Annex III organisations to request liaison status to ISO/IEC TC/SC encouraging their active support in the vote.
o will continue looking for ways to improve smooth access of Annex III organisations to ISO/IEC work focusing on harmonised standards areas.

NSBs AND NC:
o To actively support votes in ISO/IEC for Annex III liaison requests.

EU ORGANISATIONS REPRESENTING SMEs, CONSUMERS, ENVIRONMENTAL AND SOCIAL INTERESTS:
o to inform CEN and CENELEC about their plans to request liaison status with ISO/IEC TC/SC. Such information would allow CEN and CENELEC to inform their members about the need to support the liaison request.

EUROPEAN COMMISSION:
o Explore options under Regulation 1025/2012 to optimise resources for Annex III organisations to adequately influence the more costly international standards-making.

Recommendation 3: Develop policy alignment and guidance for European harmonised standards being passed to international level for development

Since harmonised standards are part of EU law after they are cited in the OJEU, the European Commission should develop guidance on the conditions regarding when and how ESOs can transfer the development of standards drafted in response to an EC Standardisation Request at the international level. Furthermore, checks of internationally originated standards against EU requirements are key to ensure compliance of the deliverables.

THE EUROPEAN COMMISSION:
o To provide guidance for CEN-CENELEC to offer the work on harmonised standards to ISO/IEC in relation to Article 5 of Regulation 1025/2012 in a policy document (e.g., the Vademecum, ESOs policy document).
o To facilitate collaboration between Annex III and NSB/NC common initiatives to promote European inclusiveness principles at international level

CEN AND CENELEC:
o To use the mechanism developed by CEN-CENELEC together with the EC for checking of standards compliance on a systematic basis and include also international based standards that are in support of EU legislation.

Recommendation 4: Promotion of inclusiveness of the ESS and the role of the Annex III organisations as best practice for international standards making

ALL EUROPEAN STANDARDISATION STAKEHOLDERS:

- o To leverage existing networks, and in direct exchanges with ISO and IEC and standardisation bodies in other regions, to encourage more balanced participation, conveying the message on the need for inclusiveness and referring to the ESS model and the role of Annex III (e.g., operational dialogues between ISO/CS and CCMC on the one hand, and IEC/CO and CCMC on the other; CEN-CLC relations with Japan, etc. Annex III – ISO/IEC relations, Annex III – ISO COPOLCO, etc.). The aim should be to explore avenues to strengthen stakeholder engagement generally, share good practices and foster new ideas on how to facilitate SME-friendly conditions and underpin the effective participation of civil society in standardisation.
- o To use the existing networks also for learning from the other global players for enhancing and improving European perception of inclusiveness.
- o To consider bringing the case for inclusiveness in light of the review of WTO principles for the development of international standards. Such a revision could address the openness criteria, moving towards the inclusiveness principle, and the need to involve societal stakeholders and SMEs largely underrepresented within international standardisation fora.

Recommendation 5: Conduct a specific analysis on inclusiveness and participation for the particular case of ICT standardisation in international standardisation bodies

While this analysis focuses on participation in ISO and IEC, a significant share of standards is today developed in the field of information and communication technologies (ICT). This field has intrinsic features and requires its own deep dive analysis. **ICT specifications and standards** do not only ensure that products can connect and interoperate with each other, they are also key to fulfilling broader policy objectives such as data protection, privacy and security by design, and to ensure the competitiveness of the European digital sector. Such standards are developed in Europe by ETSI, and internationally within ITU-T and other organisations outside the ESOs - for instance by IEEE, W3C, OASIS foundation or IETF to mention a few – and are also outside the scope of the Standardisation Regulation 1025/2012. The possibilities for participation of European societal stakeholders and SMEs in these fora remains however largely unexplored, is potentially complex, and deserves greater attention in a future analysis.

DIGITAL SME:

- o to explore the possibility of a similar analysis to the current mapping and assessment to gather the experiences of European societal stakeholders and SMEs in the field of information and communication technologies (ICT) in particular to identify needs for support and potential improvement.

Annexes

Annex 1 Overview of the ISO/IEC rules applying to liaison categories

Table 1 — Liaison categories

Category	A	B	C
Purpose	To make an effective contribution to the work of the committee.	To be kept informed of the work of the committee.	To make a technical contribution to drafting standards in a Working Group.
Eligibility	— Not for profit — Legal entity — Membership-based (worldwide or over a broad region) — Relevant competence and expertise — Process for stakeholder engagement and consensus decision-making (See clause 1.17.6.1 for full details)	Intergovernmental Organizations only — Not for profit — Legal entity — Membership-based (worldwide or over a broad region) — Relevant competence and expertise — Process for stakeholder engagement and consensus decision-making (See clause 1.17.6.1 for full details)	— Not for profit — Relevant competence and expertise — Process for stakeholder engagement and consensus decision-making (See clause 1.17.6.2 for full details)
Level	Committee	Committee	Working Group
Participation	Participate in committee meetings, access documents, may appoint Experts to WGs, and these Experts may serve as Convenors or Project Leaders.	To have access to committee documents and be able to observe committee meetings.	Full participation as a member of the WG (but cannot be Convenor or Project Leader).
Rights and obligations	No voting rights, but can comment (comments are given the same treatment as comments from member bodies). Can propose new work items (see clause 2.3.2).	No voting rights, but can comment (comments are given the same treatment as comments from member bodies). Cannot propose new work items.	Experts can attend committee meetings if expressly invited by the committee, but only as observers. Cannot propose new work items.

Source: ISO/IEC Directives (V03/2023), Part 1 and Consolidated ISO Supplement, clause 1.17, p.30.

Annex 2 CEN and CENELEC in Figures
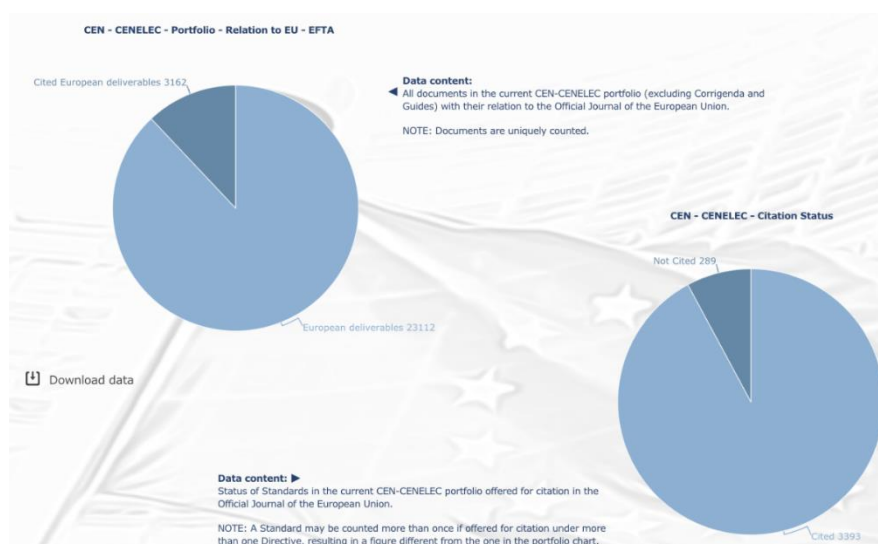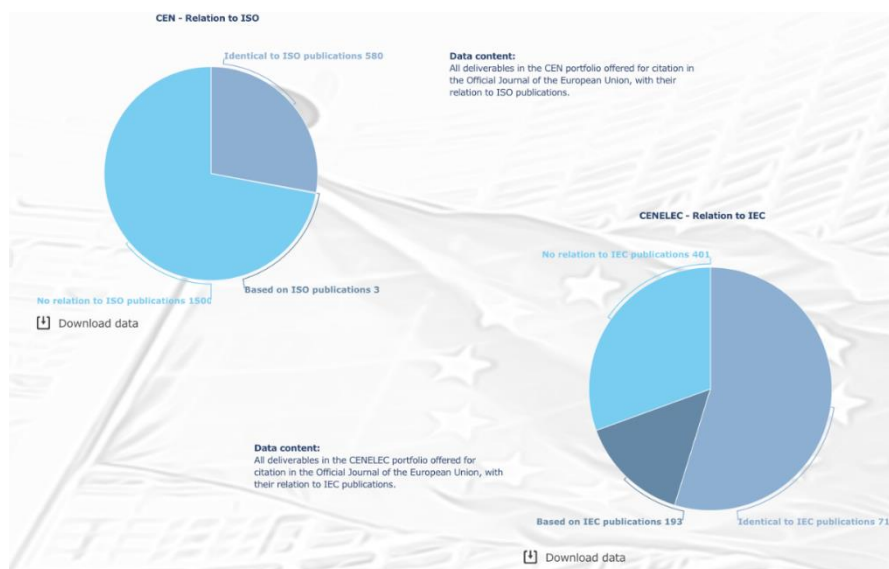
Source https://www.cencenelec.eu/stats/CEN_CENELEC_in_figures_quarter.htm (excerpts, October 2023).

Annex 3 European civil society and SME organisation's established liaisons with ISO and IEC

	ISO	IEC
ANEC	Total number of liaisons: 25 A liaisons: 23 B liaisons: 0 C liaisons: 2	Total number of liaisons: 7 A liaisons: 6 B liaisons: 0 C liaisons: 1
ECOS	Total number of liaisons: 38 A liaisons: 37 B liaisons: 0 C liaisons: 1	Total number of liaisons: 13 A liaisons: 11 B liaisons: 0 C liaisons: 2
ETUC	Total number of liaisons: 14 A liaisons: 14 B liaisons: 0 C liaisons: 0	Total number of liaisons: 0 A liaisons: 0 B liaisons: 0 C liaisons: 0
SBS	Total number of liaisons: 38 A liaisons: 37 B liaisons: 0 C liaisons: 1	Total number of liaisons: 1 A liaisons: 1 B liaisons: 0 C liaisons: 0

Source: ISO and IEC websites (excerpts, January 2025).