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IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on European standardisation, repealing Regulation (EU) No 1025/2012 of the European Parliament and of the Council

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Glossary

Term or acronym	Meaning or definition
AI	Artificial Intelligence
Annex III	Specific list of societal stakeholder organisations recognised under Regulation (EU) No 1025/2012: SBS (SMEs), ANEC (consumers), ECOS (environment) and ETUC (workers).
Annex Z	An annex to harmonised standards that identifies the legally relevant parts of the standard offered by ESOs
ASTM International	American Society for Testing and Materials International, an organisation that develops and publishes voluntary consensus standards for materials, products, systems and services
AUWP	Annual Union Work Programme on European Standardisation
CEN	European Committee for Standardisation (general sectors)
CENELEC	European Committee for Electrotechnical Standardisation (electrical engineering and electrotechnical matters)
CJEU	Court of Justice of the European Union
Common Specification (CS)	Technical specifications adopted by the Commission as a fall-back to harmonised standards when they are not available
EN	European Norms (European Standards): standards developed by CEN, CENELEC and ETSI with a harmonisation effect across their members.
ESO	European Standardisation Organisation, as defined in the Annex I of the Standardisation Regulation (CEN, CENELEC and ETSI).
ESS	European Standardisation System
ETSI	European Telecommunications Standards Institute (information and communication technologies).
HAS	Harmonised Standards consultants: external technical experts who support the Commission by assessing the compliance of technical standards with EU law.
hEN	Harmonised European Norms (harmonised standards): European standards developed in response to a request (a "standardisation request") from the Commission and, once cited in the Official

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	Journal of the European Union, can provide a presumption of conformity with relevant EU legislation
HLF	High-Level Forum on European Standardisation, an expert group of the Commission
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers, a technical professional organisation that is a SDO
ISO	International Organisation for Standardisation
ISOs	International Standardisation Organisations (generic term referring to all international standardisation organisations. Not to be confused with ISO, which refers to a specific organisation).
ITU	International Telecommunication Union
NLF	New Legislative Framework
NSB	National Standardisation Body, the national standardisation organisation of EU and EEA Member State.
OPC	Open Public Consultation
SDOs	Standards Development Organisations (generic term for any entity - private or public - whose primary activity is developing technical standards through a consensus-based process).
SMP / SMCP	Single Market Programme and proposed Single Market and Customs Programme
TC	Technical Committee, specialised bodies of SDOs responsible for developing and maintaining standards
3GPP	3rd Generation Partnership Project, global collaboration that develops and maintains standards for mobile telecommunications, including 3G, 4G, and 5G networks

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1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Political context

Standardisation is a key enabler of a well-functioning EU internal market: standards facilitate the exchange of goods and services between Member States, contributing to the harmonisation of the internal market. By ensuring interoperability, quality and consumer trust, standards facilitate market access and reduce internal market fragmentation. Standardisation has been at the core of the internal market harmonisation under the New Legislative Framework (NLF)[1] adopted in 2008. Harmonised standards (hENs), adopted by European Standardisation Organisations (ESOs)[2] following a request from the Commission under the Standardisation Regulation[3], are an **important simplification tool for businesses**: they provide access to the entire internal market through presumption of conformity, simplifying compliance and cutting conformity costs.

Standardisation is also increasingly becoming an industrial policy tool. Standards are an essential building block of the innovation process; they allow research and innovation results to spread and turn into market-ready solutions, contributing to the competitiveness of market operators. Fast standardisation can provide a first-mover advantage in technological races, facilitate the adoption of new technologies and give an edge to industrial ecosystems in the international competition. Standards are also a tool to turn policy objectives – such as decarbonisation, digitalisation, accessibility and respect for fundamental rights – into scalable, globally recognised technical solutions. Lastly, standardisation is one of the battlegrounds of international competition; access to international markets is dependent on compliance with international standards, and the ability of the EU to influence international standards directly impacts the competitiveness of EU industries and the capacity of the EU to implement its strategic autonomy agenda.

The European Council Conclusions of March 2026[4] highlighted the urgent need to "*boost the Union's competitiveness, increase its resilience and enhance its strategic autonomy and economic security*", launching the One Europe, One Market roadmap with the deepening and integration of the internal market at its core. The European Council called for "*enhancing enforcement of EU standards*" as a priority. This follows up the Commission's **Competitiveness Compass**[5], and the **Single Market Strategy** of April 2025[6], which identified the slow and unpredictable standardisation process in support of EU legislation and policies as

[1] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and 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, OJ L 218, 13.8.2008, pp. 82–128 (hereafter the NLF).
[2] ESOs are listed in the Annex I of the Standardisation Regulation. They are the *Comité Européen de Normalisation* (CEN), the *Comité Européen de Normalisation Electrotechnique* (CENELEC) and the European Telecommunications Standards Institute (ETSI).
[3] Regulation (EU) 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, OJ L 316, 14.11.2012, p. 12 (hereafter the Standardisation Regulation).
[4] EUCO 1/26, European Council meeting (19 March 2026) – Conclusions
[5] A Competitiveness Compass for the EU, COM(2025) 30 final, 29.1.2025, which identified the opportunity for "*making standard-setting processes faster and more accessible, in particular for SMEs and startups*".
[6] The Single Market: our European home market in an uncertain world, COM(2025) 500 final, 21.5.2025.

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one of the "terrible 10" of the Single Market – the 10 main barriers to its completion – and announced a review of the Standardisation Regulation[7].

The Commission announced in its Work Programme 2026[8] that the revision of the Standardisation Regulation will take place alongside **the European Product Act** (EPA)**.** The upcoming EPA will encompass the revision of the **three pillars of the EU product legislation framework**: standardisation, market surveillance[9] and the NLF. The joint revision of these three pillars will introduce a new framework for product legislation in the EU, better suited to the realities of 21st-century products and more capable of ensuring that the internal market remains a key asset for EU competitiveness and strategic autonomy.

1.2. Legal context

The Standardisation Regulation organises the functioning of the European Standardisation System (ESS), the current partnership between the Commission, ESOs and National Standardisation Bodies (NSBs) and stakeholders[10] to develop standards and standardisation deliverables[11] to support Union legislation and policy. The primary focus of the Regulation is the process for delivering hENs, defined as a '*European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation*"[12]. The functioning of the ESS is described in more details in Annex 8.

The **Standardisation Regulation supports the NLF**, which provides a blueprint for EU product legislation and aligns 31 legal acts covering a wide range of product markets. One of the key principles of the NLF is to provide a presumption of conformity to products complying with the hENs supporting the legislation applicable to those products, allowing products to freely circulate within the internal market.

Over time, **additional legislation** beyond product harmonisation legislation has been relying on the Standardisation Regulation, covering notably digital technologies, cybersecurity, data or Artificial Intelligence (AI). In addition, key policy initiatives have leveraged standardisation as a tool to implement their objectives, notably in the field of the green transition, such as the Green Deal and the Clean industrial deal[13], and of sectoral industrial strategies, such as the European Strategy for Housing Construction and the Bioeconomy strategy[14].

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[7] The European Economic and Social Committee supported the revision in its Opinion Strategic standardisation for a stronger single market (own-initiative opinion), INT/1120.
[8] 2026 Commission work programme and annexes, COM(2025) 870 final, 21.10.2025.
[9] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products, OJ L 169, 25.6.2019, pp. 1–44.
[10] The European Standardisation System is currently limited to the ESOs as the only organisations allowed to deliver standards and standardisation deliverables in support of Union legislation and policies but could in the future be extended to other standardisation organisations – see Section 5.
[11] A 'European standardisation deliverable' means any other technical specification than a European standard, adopted by a ESO for repeated or continuous application and with which compliance is not compulsory – see Standardisation Regulation, Article 2 Definitions.
[12] Standardisation Regulation, Article 2 Definitions.
[13] The European Green Deal, COM(2019) 640 final, 11.12.2019; The Clean Industrial Deal: A joint roadmap for competitiveness and decarbonisation, COM(2025) 85 final, 26.2.2025.
[14] The European Strategy for Housing Construction: a more competitive and productive construction industry, COM(2025) 991 final, 16 December 2025; A Strategic Framework for a Competitive and Sustainable EU Bioeconomy, COM(2025) 960 final, 27.11.2025.

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The Standardisation Regulation was amended in 2022[15] following the Standardisation strategy[16] to ensure that decisions related to the implementation of standardisation requests by the ESOs are taken by NSBs of the EU and the EEA only. In May 2025, the Commission proposed targeted modifications to key product legislation of the NLF under its **Omnibus IV proposal**[17] to introduce the possibility for the Commission to adopt common specifications (CS) as a fall-back option in case the ESOs fail to deliver hENs, expanding the number of Union legislation already including such a possibility. This will contribute to improve legal certainty for companies by enabling them to benefit from presumption of conformity through CS even if hENs are not available.

The Court of Justice of the European Union (CJEU) has clarified that **hENs form part of EU law**[18] and that there is an overriding public interest in their disclosure[19], based on the principles of rule of law and transparency. The Commission, in cooperation with ESOs, has implemented this judgment by providing access to hENs through readability platforms[20]. EU legislation also directly references standards or technical specifications from ESOs or other standard developing organisations (SDOs), without having first requested them under the Standardisation Regulation. Such directly referenced standards[21] may be made mandatory by the legislative act, in which case they are made accessible through the readability platforms[22].

While these standards are thus used to support a wide range of Union legislation and policy with different legal and policy effects, **they only represent a small part of the activities of the ESOs**. hENs make up only 12 % of all European standards[23] developed by the three ESOs (CEN, CENELEC and ETSI)[24]. This initiative primarily focuses on the delivery of standards for Union legislation and policy – see Annex 7. However, there are clear synergies and inter-linkages between the activities of the ESOs as providers of standards for legislation or policy use and as a provider of standards that are purely market-driven.

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[15] Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 1025/2012 as regards decisions of European standardisation organisations concerning European standards and European standardisation deliverables, OJ L 323, 19 December 2022, p.1.

[16] An EU Strategy on Standardisation - Setting global standards in support of a resilient, green and digital EU single market, COM(2022) 31 final, 2.2.2022.

[17] COM(2025) 504 final, 21 May 2025. See Annex 9 for more details on the Omnibus IV proposal.

[18] Judgment of 27 October 2016, *James Elliott Construction* Ltd *v Irish Asphalt Ltd.*, C-613/14, EU:C:2016:821.

[19] Judgement of 5 March 2024, *Public.Resource.Org and Right to Know v Commission,* C-588/21 P, EU:C:2024:201.

[20] Following individual requests, those that have been disclosed under Regulation (EC) No 1049/2001 (Access to Documents Regulation) can be freely accessed on the online national readability platforms of NSBs in a read-only format. hENs based on ISO or IEC standards can be accessed through the Commission's readability platform after individual requests for access to documents.

[21] As of December 2025, the Commission estimates the number of standards directly referenced in EU legislation to be around 3 500, supporting over 1 100 different legal acts and originating from 39 different SDOs. The large majority comes from the ESOs (48%) and ISO and IEC (37%), while the remainder originates from various other SDOs (15%).

[22] The CJEU noted that those standards should be freely accessible in its judgment of 21 April 2026, *Nederlandse Voedsel- en Warenautoriteit and Others*, C-155/24, ECLI:EU:C:2026:327, para 34 and 38.

[23] Standards adopted by ESOs are European standards (EN); they have a harmonisation effect in the internal market as ESOs ensure they are no conflicting national standards with ENs.

[24] As of April 2026. Data on hENs stem from Commission analysis based on the eNorm system, that consolidates information on standardisation in support of Union legislation and policy. These shares vary across ESOs (13 % for CEN, 10 % for CENELEC and ca. 9 % for ETSI). hENs from CEN represents 70 % of all hENs, CENELEC 25 % and ETSI 5 %.

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1.3. Link with other initiatives

The revision of the Standardisation Regulation will take place in parallel with the revision of the Market Surveillance Regulation and of the NLF as part of the upcoming **European Product Act**. These initiatives are closely related, as product legislation falling under the NLF is among the EU legislation most dependent on the delivery of high-quality hENs for its implementation. The NLF and the Market Surveillance Regulation organise the accreditation, conformity assessment and the enforcement framework in the EU, which is largely dependent on the standardisation system for its effective functioning.

The future **Single Market and Customs Programme (SMCP)**[25] under the next Multi-annual Financial Framework 2028-2034 will also play an important role in the future of the ESS. One of the objectives of the current Single Market Programme (SMP)[26] is to "*ensure the effective functioning of the internal market through standardisation processes*" and is instrumental in supporting the activities of ESS. The future SMCP will continue to pursue this objective and will be the main EU financial instrument to support the functioning of the ESS.

2. PROBLEM DEFINITION

2.1. What are the problems?

While the Standardisation Regulation has improved the functioning of the ESS, its recent evaluation (the Evaluation)[27] concluded that **the current framework is unfit to meet the challenges** arising from the need to provide access to standards, rapid technological developments, and intensifying international competition. This diagnosis supported similar conclusions from the Letta and Draghi report, highlighting that "*Member States do not systematically exploit the benefits of coordination at the EU level, of standardisation and interoperability"*[28] and that standardisation is essential in supporting EU competitiveness in strategic areas such defence, transport and clean and emerging technologies[29]. The problem analysis in this Impact Assessment complements the Evaluation's findings with desk research, public and targeted consultations, interviews, workshops and sectoral case studies.

2.1.1. Problem 1: lengthy and complex standardisation process prevents timely availability of standards

The process of developing hENs is too slow to meet the legislative needs and keep pace with technological developments[30]. While the Evaluation shows an overall decrease in the average time to develop hENs[31] from about 9 to 10 years before 2012 to around 6 years today, this

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[25] Proposal for a Regulation of the European Parliament and of the Council establishing the Single Market and Customs Programme for the period 2028-2034, COM(2025) 590_1 final, 3.9.2025.
[26] Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 Single Market Programme, OJ L 153, 3.5.2021, pp. 1–47.
[27] Evaluation of the Regulation (EU) No 1025/2012 on European standardisation, SWD(2025) 170 final, 23.6.2025 (hereafter: Evaluation).
[28] Draghi Report, The future of European competitiveness, Part B, Section 1, Chapter 7, 2024.
[29] Letta Report, Much More than a Market, 2024.
[30] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fraunhofer ISI, Intellera Consulting and Trinomics B.V, *Evaluation study of the regulation (EU) 1025/2012 on European standardisation – Final report*, p. 99, Publications Office of the European Union, 2025 (hereafter Evaluation Study).
[31] *Ibid*, pp. 100-101.

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length remains incompatible with the speed of technological, industrial and innovative cycles, and longer than that of the EU main international competitors[32]. The magnitude of delays and their cost implications varies across sectors and products, and the available evidence does not allow a systematic sector-by-sector quantification. The analysis therefore uses aggregated evidence and conservative assumptions to characterise the scale of the problem.

Delays in delivering hENs are frequent, and their quality often fails to meet the requirements set out in the request, especially in fast-moving technological fields such as AI, cybersecurity and green technologies. Over the past 5 years, the Commission has repeatedly extended deadlines for standardisation requests, amending 21 % of the adopted requests, thereby creating uncertainty for businesses on when standards will be available[33]. For instance, the hENs requested by the Commission to support the AI Act[34] are delayed by at least two years and have not been delivered yet, while standards supporting the Cyber Resilience Act (CRA)[35] are also expected to be delivered after the deadline. In another strategic area like raw materials, despite clear targets set by the EU Battery Regulation[36] and standardisation intentions of the Critical Raw Materials Act[37], the adoption of requests is late. As the High-Level Forum on European Standardisation (HLF)[38] highlighted, standardisation in these fields is essential to ensure a global level playing field, improve transparency across the value chain and strengthen the Union's strategic autonomy. Such delays hinder the EU ability to meet its regulatory targets and weaken its position in global value chains. The situation is similar in the field of medical devices, where the delivery of standards has been postponed by at least four years.

The delays and uncertainty as to when hENs will be delivered by the ESS impose **additional compliance costs on businesses, in particular SMEs**. When hENs are unavailable, businesses must rely on more costly third-party conformity assessments[39]: businesses spend between EUR 30 000 and EUR 80 000 a year per undertaking on the services of notified bodies[40]. The 2023 impact assessment for the revision of the Toy Safety Directive estimated that on average EUR 500 is required per new toy model for self-certification based on a hEN, and EUR 1 000 for a conformity assessment by a third-party[41] – an estimate significantly higher for more

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[32] ASTM International, a US standardisation organisation, claims an average standard development time of 18 months for a new standard and less than 6 months for revisions of existing standards (ASTM International, *How are ASTM standards developed?*, 2025). IEEE, an international association developing standards, has conducted nearly one revision per year of the IEEE 802.11 standards on wireless local area networks, compared with only 9 revisions in 21 years for comparable European standards.

[33] Commission analysis based on eNorm.

[34] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), OJ L, 2024/1689, 12.7.2024.

[35] Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements, OJ L, 2024/2847, 20.11.2024.

[36] Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, OJ L 191, 28.7.2023, pp. 1–117.

[37] Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials, OJ L 1252, 3.5.2024.

[38] HLF, Workstream 15 on Critical Raw Materials - conclusions and recommendations.

[39] The availability of a hENs does not automatically exempt a product from undergoing a third-party conformity assessment as it can be a requirement for certain categories of risky or complex products. However, even in those cases, the assessment cost becomes substantially lower as it only concerns conformity with the hEN rather than conformity directly with the essential requirements.

[40] Notified bodies services are independent conformity assessment activities (testing, inspection, and certification) performed by designated organisations to verify that products meet EU regulatory requirements. Data sourced from the Evaluation Study.

[41] SWD(2023) 269 final, 28.6.2023.

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complex products. The difference in costs between self-certification and certification by notified bodies is reinforced by the very limited costs of a hEN, between EUR 100 and EUR 120 on average across the EU[42]. Overall, the Evaluation estimates an average cost saving for each undertaking of EUR 3 700 per hEN used for conformity assessment[43].

Beyond the financial burden on businesses, **non-availability of hENs can also slow developing and scaling of innovative solutions,** weaken the EU ability to respond to global technological developments and emerging risks, as well as undermine its role as global standard-setter[44]. In sectors like unmanned aircraft systems, only one of eight requested hENs was available before the transition deadline, forcing manufacturers to rely on more lengthy and costly third-party conformity assessments. The Radio Equipment Directive's cybersecurity requirements required a postponed application date because the underlying hENs were not ready in time. These delays leave room to more agile and active SDOs to influence the international standardisation process[45].

In the **Open Public Consultation (OPC)** for this IA, 66 % of participants (397 out of 599) reported to have encountered situations in which hENs were not available or made available with delays. 49 % (296 out of 599) agreed that hENs sufficiently reflect the state of the art.

2.1.2. Problem 2: lack of balanced stakeholder participation challenges quality of standards

The Evaluation highlights **insufficient participation of SMEs, civil society, academia and research organisations** in the standardisation process[46]. This affects the functioning of the ESS, including the quality of hENs and their timely delivery, as standardisation significantly benefits from the participation of societal stakeholders to enhance its legitimacy, acceptability and relevance[47]. The lack of diverse input can also hinder the development of inclusive and forward-looking standards. While the introduction of the Annex III organisations[48] in the Standardisation Regulation has improved inclusiveness at EU level, this has not always translated into effective participation and influence, in particular at national level. The Evaluation found that representation remains insufficient for civil society organisations, SMEs and research organisations, especially in areas with significant societal implications, such as accessibility, fundamental rights and AI, or where competing technologies are still under consideration, including where newcomers or smaller organisations seek to contribute[49]. People with disabilities continue to face barriers to participation, and accessibility considerations are not always adequately reflected in the standardisation process.

The Evaluation's public consultation confirmed these concerns, with stakeholders indicating that reliance on industry technical expertise may not sufficiently address public-interest

[42] The average price of a hEN has been provided by the ESOs and NSBs at the NSB workshop. It is an average across Member States. Most companies however buy standards via subscription models.
[43] Evaluation, p. 48.
[44] Evaluation and Draghi Report – The Future of European competitiveness (2024).
[45] India and China SDOs claim development times of less than 18 months; China reported meeting this timeframe for ultra-high-definition video technology, green computing and the Internet of Things standards.
[46] Evaluation, p. 67.
[47] Impact assessment study, p. 16.
[48] The Annex III organisations are: ETUC representing social interests, ANEC representing consumers, ECOS representing environmental interests and SBS representing SMEs. They are eligible to Union financing under Article 16 of the Standardisation Regulation to represent their interest in the EU standardisation process.
[49] Evaluation, p. 32.

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considerations, which are essential for hENs. In practice, large companies tend to dominate technical work, particularly in complex fields such as data governance or environmental labelling, where participation requires specialist knowledge[50] and engagement at national, European and international levels. This can limit the diversity of expertise and reduce the relevance, legitimacy and acceptability of standards[51] – further discouraging SMEs from participating in the process as standard deliverables are less adapted to their specific needs. Empirical evidence from the Evaluation's public consultation shows that 39 % of respondents strongly agreed and 42 % agreed that promoting stakeholder engagement to ensure standards meet market and consumer needs is essential for the ESS's strategic goals. Empirical research on standardisation governance supports a direct link between participation and standards quality[52]. Empirical evidence on environmental governance also shows that stakeholder participation has a measurable positive effect on governance outcomes, with the representation of non-economic interests, including civil society, being associated with stronger outcomes, while the concentration of economic interests is associated with weaker ones[53].

Stakeholder participation also affects the timeliness of hEN delivery in different ways. Broader participation can lengthen some phases of the process because it requires reconciling a wider range of views. At the same time, excluding key specific expertise can cause delays in the standardisation process, as seen for the standard for equestrian helmets (EN 1384), where insufficient input from consumer associations led to very long duration of standardisation (over 10 years). Thus, while broader participation may extend certain phases, ultimately, it can also support more efficient and widely accepted outcomes.

Furthermore, the **growing lack of experts** available to engage in standardisation has become a concerning trend in Europe. This is driven by several factors, including an ageing workforce, a gradual loss of expertise, a declining willingness of EU industry to invest time and resources into standardisation activities as well as an insufficient number of EU firms active in specific technological fields[54]. This issue has been formally recognised at policy level: 22 Member States and 26 member organisations of the HLF signed a pledge in 2023 to contribute to the education of the new generation of European standardisation professionals[55]. In parallel, industry associations have identified the lack of education, training and general awareness on standardisation as key issues requiring attention[56]. Participation is further constrained by limited incentives for the industry, in particular for SMEs facing resource constraints and for which the expected costs to participate in standardisation outweigh the perceived benefits.

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[50] For case of ETSI, 27 % of its membership is made of SMEs (ETSI website).

[51] Under-representation of those stakeholders leads to standards that lack legitimacy, risk reflecting narrow interests and more susceptible to rejection or legal challenge. Impact assessment study, p. 16-17.

[52] Wiarda, Doorn and Van de Kaa (2024), ranking eighteen criteria for the quality of standardisation processes, find that diversity of participation is the single most important contributing factor to the quality of standardisation, ahead of all other criteria tested. Wiarda, M., Doorn, N. and Van de Kaa, G. (2024), *Towards responsible standardisation: investigating the importance of responsible innovation for standards development*, Technology Analysis & Strategic Management.

[53] Newig, J., Jager, N.W., Challies, E. and Kochskämper, E. (2023), *Does stakeholder participation improve environmental governance? Evidence from a meta-analysis of 305 case studies*, Global Environmental Change. Beyond standardisation specifically, the broader governance literature supports that inclusive stakeholder engagement improves the quality of regulatory and rule-making processes: the OECD finds that meaningful consultation strengthens the evidence base available to decision-makers and improves both the legitimacy and the practical workability of resulting rules. OECD Regulatory Policy Outlook 2025.

[54] Evaluation, p. 22 and 35.

[55] HLF: Pledge on education & skills on standards.

[56] Evaluation, p. 165.

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In the **OPC** for this IA, the inclusiveness of the ESS is not perceived as the main challenge, as the same high proportion of respondents (67 %, 401 out of 599) considered both the national and the European level to be inclusive.

2.1.3. Problem 3: requirements for free access to hENs create uncertainty regarding the sustainability of the ESS

Several judgments of the CJEU[57] underlined that hENs, the references of which have been published in the Official Journal of the European Union (OJEU), **form part of EU law owing to their legal effects**[58]. Therefore, an overriding public interest justifies their disclosure, based on the principles of the rule of law, transparency, openness and good governance[59]. As a result, hENs may no longer be considered as purely technical documents aimed at facilitating manufacturers' access to the EU market: they are now recognised as documents which form part of EU law and must be freely accessible. The CJEU recently held that the same rationale should apply to standards which are directly referenced in the OJEU[60].

These requirements to provide free access to hENs may **challenge the financial equilibrium of the ESS**, and in particular of CEN/CENELEC and its member NSBs, which contribute to developing hENs in exchange for the exclusive right to sell them in the EU – see Annex 8. While the members of CEN/CENELEC operate on a not-for-profit basis, providing access to hENs free of charge may lead to a decrease in their revenues and alter their business model, limiting their ability to engage in standardisation activities to support Union legislation and policy. ETSI is not directly impacted[61], as all its standards are available free of charge for consultation and download on its website. The assessment of this problem is affected by significant data constraints, notably because key stakeholders seek to preserve the confidentiality of business information and NSBs do not specifically track sales of hENs. The analysis therefore relies on data collected through bilateral exchanges, interviews and validation workshops with stakeholders.

The negative effects on the functioning of the ESS have already been noticeable, particularly in relation to international standardisation organisations. Indeed, CEN/CENELEC submitted no new hENs based on ISO and IEC international standards to the Commission for assessment[62] between May 2024 and October 2025 (for ISO) and between March 2024 and January 2026 (for IEC). This interruption was directly linked to uncertainties regarding the impact that disclosing their standards in line with the judgements of the CJEU would have on ISO and IEC. As a result, delays in the implementation of EU legislation arose, creating uncertainty for manufacturers on how to demonstrate compliance with EU legislation, for example in the field of medical devices.

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[57] *James Elliott Construction Limited v Irish Asphalt Limited*, C-613/14 and *Public.Resource.Org and Right to Know* v *Commission*, C-588/21 P.
[58] *James Elliott Construction*, C-613/14, paragraph 40.
[59] *Public.Resource.Org and Right to Know* v *Commission*, C-588/21 P, paragraph 89.
[60] Judgment of 21 April 2026, *Nederlandse Voedsel- en Warenautoriteit and Others*, C-155/24, ECLI:EU:C:2026:327, paragraphs 34 to 38.
[61] ETSI is financed by membership fees – see Annex 8.
[62] CEN-CENELEC may adopt ISO/IEC standards as hENs and submit them to the Commission for assessment, ensuring alignment between hENs and existing global standards for efficiency and coherence.

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In the **OPC** for this IA, only 40 % of participants indicated that it is not difficult to identify the legally relevant content of a hEN[63] (240 out of 599), the parts of hENs that cover the essential requirements set out in sectoral legislation.

2.1.4. Problem 4: Diminishing global position and relevance of EU standards challenge EU competitiveness

Standards can be an **essential instrument of international competitiveness.** Countries or regions that project their national standards to the international stage at an early stage can gain a competitive advantage by influencing global markets towards their own native technology, especially in emerging markets. For instance, China's growing influence in ISO's committees, allows it to shape global rules to favour its technologies and create lock-in effects in emerging markets through its 90 Belt and Road agreements[64]. At the same time, fragmentation of standards may act as a trade barrier for companies, especially for SMEs. According to the World Bank, nearly 90 % of world trade is now shaped by non-tariff measures, mostly linked to standards – up from 15 % in the late 1990s[65].

This is reflected in the strategy of **several jurisdictions that prioritise standardisation** as an instrument of their competitiveness and national security agenda. In 2021, China issued an ambitious Standardisation Strategy[66], integrated into its Belt and Road Initiative, whereas in 2023, the US published its National Standards Strategy for Critical and Emerging Technology, and revised its United States Standards Strategy in early 2026[67]. The US reaffirmed that US standards should "*drive the world forward*" in AI, biotech and quantum computing, which it identified as "*core, vital national interests*"[68]. Similarly, the EU fosters the strategic use of standards to support its international competitiveness and technological sovereignty, a key objective of its 2022 Standardisation Strategy.

While the EU maintains strong participation in international standardisation organisations (ISOs), **its influence is gradually fading, particularly in key emerging technologies**. The European and international standardisation systems are tightly connected: CEN aligns over one-third and CENELEC more than 80% of their standards with ISO and IEC (see Annex 11) [69]. In 2025, NSBs from EU Member States held the secretariat of 300 technical committees (TCs) and sub-committees (38 % of the total in ISO, slightly below the 40 % in 2010[70]). However, the EU only holds two out of eleven secretariats for the strategic technologies identified in the Competitiveness Compass as "*the technologies that will matter for tomorrow's economy*"[71]. Stakeholders also noted China's growing influence in ISOs through the active participation of

[63] Only certain sections of hEN may be relevant to the essential requirements set out in sectoral legislation. These sections are usually identified in the Annex Z of the hEN, which was introduced in 2015.
[64] *Standardisation with Chinese Characteristics? The Missing Pillar in Rebooting Europe's Industrial Policy*, CKN & Clingendael Report, 2025
[65] Standard for Development Overview, World Bank Development Report 2025.
[66] *Outline for the Development of National Standardization*, Beijing, 2021.
[67] United States Government National Strategy for Critical and Emerging Technology, May 2023; United States Standards Strategy 2025.
[68] National Security Strategy of the USA, November 2025.
[69] CEN CENELEC in figures - Quarterly, 2026 Q1
[70] ISO in Figures.
[71] A Competitiveness Compass for the EU, p. 5. The technologies identified are AI, semiconductor and quantum technologies, advanced materials, biotechnologies, clean energy technologies, robotics, space technologies, connected and autonomous mobility.

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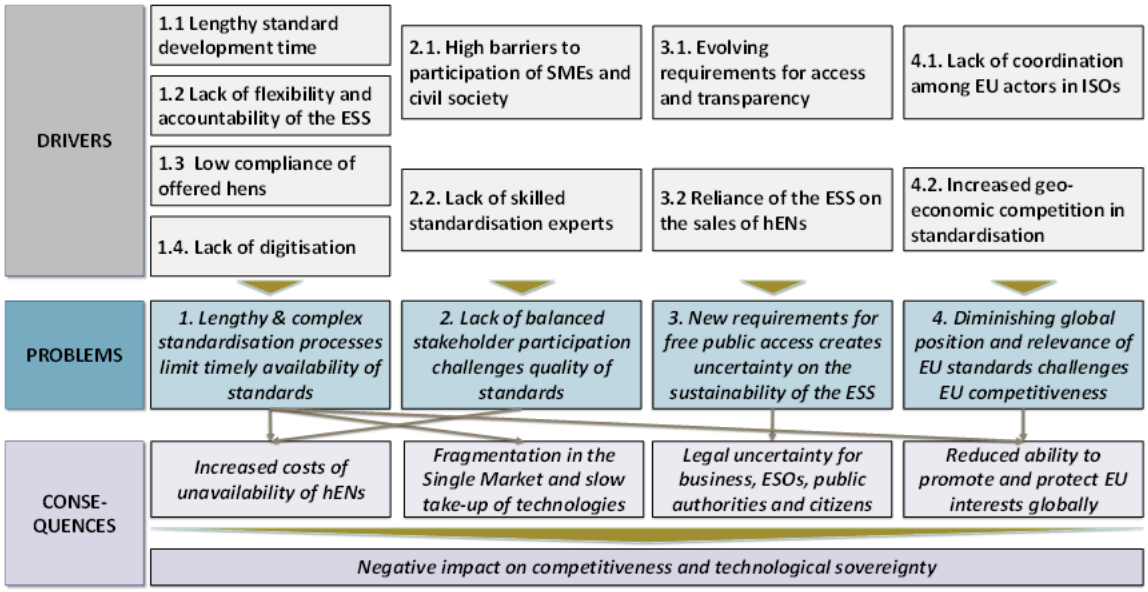
its experts[72]. Thus, the EU's limited influence in emerging technologies, coupled with the primacy of international standards, could impair its ability to protect its values, interests, and competitiveness. This decline thus risks directly affecting the ESS.

In the **OPC** for this IA, more than half of the respondents (65 %, 391 out of 599) believe that the EU has a strong influence on standardisation internationally, with trade unions being the only stakeholder group in which respondents opposed to this view.

2.2. What are the problem drivers?

The problem tree in Figure 1 below summarises the problems, drivers and consequences.

Figure 1: Problem tree



2.2.1. Drivers related to Problem 1

Driver 1.1: Lengthy standard development time at each step of the process

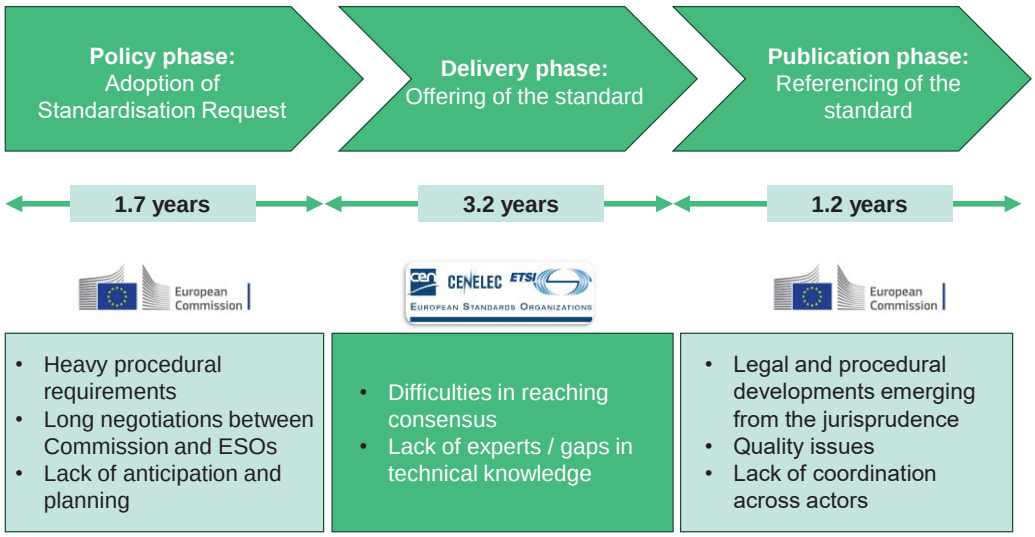
The current lack of responsiveness of the ESS lies first and foremost **in the current average delivery time of 6 years for hENs**, which is too long to cope with the speed of technological, industrial and innovative cycles. The Evaluation highlights that the speed of the standardisation process is hampered at all steps of the process: in the **policy phase**, covering the adoption of standardisation requests by the Commission, in the **delivery phase**, covering the acceptance of standardisation requests and the drafting of the standards by ESOs, and in the **publication phase**, covering submission by ESOs and the publication in the OJEU, including the compliance assessment by the Commission services.

Figure 2 summarises the **key factors**; Annex 9 provides a detailed analysis of each factor.

Figure 2: Process for adopting a hEN and key drivers for duration[73]

[72] Targeted interviews with representatives of ESOs, NSBs and the industry.
[73] Commission analysis based on the Evaluation, p. 28.

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Driver 1.2: Lack of flexibility and accountability of the ESS

Another driver of slow standard delivery is the **limited flexibility** provided by the current legal framework. The Commission may only address standardisation requests to ESOs, which in effect often means a single option as each of the ESOs has specific sectoral expertise. This exclusive reliance on ESOs can become a bottleneck, especially in niche or highly innovative sectors where they have limited expertise and where other SDOs are better placed to draft technical specifications rapidly. In specific sectors, the only way for ESOs to deliver on standardisation requests is to establish partnerships with other standards development bodies like ASD-STAN for aerospace and drones, ESA for space or W3C for eAccessibility[74] to integrate their standards into ESOs' standards (see Annex 13).

Moreover, the Commission has **limited options to change the course of a request** that will be late or whose outcome is expected to be of insufficient quality[75]. There is also no mechanism to foster standardisation when the consensus building process is blocked for other reasons (diverging commercial interests, technical difficulties to translate essential requirements)[76]. When the ESOs fail to deliver hENs, the only alternative is for the Commission to develop and adopt CS. However, this possibility does not exist for all legislation relying on hENs, although the Omnibus IV will increase this possibility.

The lack of flexibility of the ESS is compounded by **the lack of accountability and transparency** on the status and performance at each stage of the process. No joint monitoring tool between the ESOs and the Commission exists to date. While the Commission and ESOs

[74] ASD-STAN (*Association des industries aérospatiales et de défense de l'Europe – Normalisation)* is the aeronautics and defence industry association. ESA is the European Space Agency and W3C is the WorldWideWeb Consortium.

[75] This has for instance been the case in the standardisation process supporting the IA Act and the CRA. The Commission fostered the acceleration of the process with the only tool at its disposal by financing the participation of experts. It awarded grants to support standardisation process through the SMP, the StandICT.eu project and the CYBERSTAND project.

[76] One such example is the difficulty to agree on an international standard for Megawatt Charging Systems for recharging heavy-duty vehicles. Consensus on an international standard was blocked by diverging technical proposals based on different commercial interests, with the proposal made by EU and US stakeholders competing with a different solution proposed by Japan and China.

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have initiated this work following a joint Task Force[77], supporting IT tools are not yet fully operational. Moreover, beyond the legal deadline set out to ESOs for the delivery of hENs, there are no binding nor indicative deadlines on the different steps of the process, which makes performance management difficult and leads to uncertainty on whether and when hENs would be available. The adoption of standardisation requests can also be delayed by **lack of anticipation and planning,** such as the insufficient upstream coordination between research and innovation activities and standardisation processes – resulting in fragmented technical approaches and limited readiness for consensus-building when standards are needed.

Driver 1.3: Low compliance of submitted hENs

One of the root causes of delays is **the frequent misalignment of standards delivered by ESOs with the legal requirements** laid down in EU legislation as set out in the standardisation requests, leading to high rejection rates (65 % at first review, 32 % at publication stage). These compliance failures trigger repeated revision cycles, additional scrutiny, and prolonged discussions between the Commission, HAS consultants[78], experts and ESOs (see Annex 9 for more details on low compliance and its root causes).

Contributing to these failures are differing interpretations of essential requirements, insufficient legal guidance during drafting, ESO internal procedures that hinder late revisions and technical experts' difficulties with hEN formal requirements[79]. The frequently long formal objection procedure, whereby Member States can challenge the compliance of hENs with essential requirements after they have been referenced, also adds to the uncertainty on the quality and validity of hEN[80].

Driver 1.4: Limited digitalisation

The lack of digitalisation of the standardisation process is **a lost opportunity to speed up each stage of the process.** Although new ICT tools have been introduced by ESOs and NSBs, many drafting, commenting and editorial tasks continue to be done with traditional software rather than through collaborative digital platforms. Lack of a full digital lifecycle (editable formats, modern commenting, integrated review workflows) slows drafting and makes roles such as rapporteurs and editors less efficient. The Commission has digitalised its standardisation request process through the introduction of the eNorm platform, to ensure that the entire regulatory chain is traceable, searchable and interoperable.

2.2.2. Drivers related to Problem 2

Driver 2.1: High barriers to participation of SME and civil society

Despite the formal mechanisms for participation introduced by the Standardisation Regulation, the actual participation of SMEs and societal stakeholders remains **limited, particularly at national level** where EU-like regulation mandating inclusiveness does not systematically exist.

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[77] The ESOs-European Commission-EFTA Taskforce on "*Timely European Standards for a Green and Digital, Single and Global Market*" delivered its conclusions on October 2023.
[78] Harmonised Standards consultants: external technical experts who support the Commission in assessing the compliance of hENs with the essential requirements.
[79] Impact assessment study, p. 13.
[80] Evaluation, p. 27 and 35. Between 2014 and 2024, Member States filed 41 formal objections, 22 % of which led to restrictions (hence a limitation of the scope of applicability of the hEN). The mechanism functions slowly requiring on average 21 months before certainty on the hEN is provided to stakeholders.

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A 2025 Eurobarometer survey[81] of over 17 000 EU SMEs identified three main barriers: lack of resources, complexity and a perceived lack of influence.

The costs of participation remain one of the main barriers. The HLF estimated that participation in standards-development activities can take from 25 to 30 working man-days a year per company, a time and resource investment which is generally too high for SMEs[82]. The Evaluation estimated the average annual cost of participating in standardisation activities between EUR 60 000 and EUR 160 000 for an SME[83]. Moreover, financial support for SMEs participation in standardisation is limited and uneven across Member States[84]. The most common form of support is generally *ad hoc*, through facilitated access to mirror committees at national level and invitation to specific TCs meetings (60 %)[85]; SME awareness of these mechanisms remains low, particularly for government-led schemes[86]. This cost-constraint also applies to civil society organisations and research and innovation actors.

The **complexity of the standardisation process** is also a specific challenge for SMEs. The development of standards requires several consecutive rounds of drafting, technical validation and public inquiry to harmonise the conflicting commercial and legal interests of diverse stakeholders. The process requires highly specialised expertise and long-term coordination – often spanning several years – to ensure specifications are technically sound, legally compliant and interoperable across markets. For SMEs, this complexity is particularly daunting, as the sheer number of procedural steps and extensive idle periods often exceed their more limited administrative capacity.

Lastly, **the perceived lack of influence of SME and civil society** on the standardisation process discourage their participation. While Annex III organisations contribute to standardisation in CEN and CENELEC through formal opinion on final draft standards during the enquiry and voting stage, they have no formal vote in decision-making procedure. At ETSI however, they participate as full members: they have direct access to ETSI documents, can take part in the standardisation meetings and can vote on standardisation drafts, although they are usually outnumbered by the votes from the industry, which represents the majority of ETSI's members. The lack of influence of Annex III organisations is amplified by the fragmented approach at national level: between 25 % and 50 % of NSBs still do not have formal mechanisms to involve societal stakeholders[87]. They face even more difficulties to take part in standardisation at international level, which can heavily influence EU standardisation.

Driver 2.2: Lack of skilled standardisation experts

The **shortage of skilled standardisation experts** is hampering stakeholders' participation and limits the development and maintenance of high-quality standards. The Evaluation Study identifies the ageing profile of technical experts as a key structural factor affecting the ESS[88]. Assuming a retirement age of 67, approximately one quarter of the current expert pool will have

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[81] Flash Eurobarometer Survey 559 - Startups, scaleups and entrepreneurship (2025)
[82] High Level Forum on European Standardisation, Workstream 3 Report on NSB Peer Review.
[83] Evaluation, p. 46.
[84] Impact Assessment study, p. 16.
[85] High Level Forum on European Standardisation, Workstream 3 Report on NSB Peer Review (including SMEs and civil society inclusiveness), p. 9.
[86] *Ibid*, p. 10.
[87] Evaluation Study, p. 83-84.
[88] *Ibid*, p. 35.

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to be replaced by 2030[89]. This demographic imbalance creates challenges for the ESOs, notably in mobilising sufficiently specialised expertise for emerging or highly technical sectors.

The **insufficient integration of researchers** is another explanation of the insufficient participation of skilled standardisation experts. Despite recent efforts by ESOs to strengthen engagement with the research community, participation remains limited due to the cost–incentive imbalance faced by researchers[90]. Barriers are similar to those faced by SMEs and Annex III organisations, including high participation costs, but also include limited professional incentives and recognition of researchers' contribution to standardisation-related activities in academic career frameworks, despite the relevance of standardisation for the valorisation of research results. ESOs have implemented measures to facilitate researchers' participation, notably project liaison mechanisms enabling researchers to participate in TCs, horizontal groups on pre-normative research, dedicated research helpdesks, support staff, online repositories and enhanced cooperation with the Joint Research Centre[91]. The Multi-stakeholder Platform on ICT standardisation also set up a R&I Task Force linking research, innovation and standardisation. However, available evidence suggests that these measures have had a limited overall impact. The evaluation highlighted that 41 % of stakeholders did not perceive an improvement in researcher participation, while 75 % of responding research organisations considered that the Standardisation Regulation has not been sufficient in ensuring their effective involvement[92]. The main underlying factors identified include the complexity of standardisation processes, the financial burden associated with access to standards and participation (including travel costs), and the time commitment required for meaningful engagement[93].

2.2.3. Drivers related to Problem 3

Driver 3.1: Evolving requirements for access to standards

The judgments of the CJEU as regards the **legal nature of standards in EU law** have had a significant impact on the functioning of the ESS, and in particular on CEN and CENELEC and their member NSBs, which had to develop readability platforms to allow the public to freely consult hENs. The CJEU did not specify how hENs should be disclosed, notably whether they should be available for consultation or download and if access concerns the entire standard or only the legally relevant part. Similar questions remain for directly referenced standards, as free access to those must be "*general, effective, without charge, and non-discriminatory*"[94]. The uncertainty regarding the appropriate conditions to provide access to hENs is reinforced by the fact that operational solutions implemented by CEN, CENELEC and the Commission through readability platforms are being **challenged in Court**. Opponents argue that these solutions fall short of the requirements stemming from the principles of rule of law and transparency[95], and that hENs should be made directly and systematically available.

Another consequence of the judgments of the CJEU is the **need for greater transparency** of the standardisation process for legislative and policy purposes. Standards forming part of EU law should be developed along the principles of transparency, openness and good governance.

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[89] European standardisation panel survey – Final report (2024), p. 21.
[90] Evaluation Study, p. 118.
[91] Evaluation Study, p. 84-85. See JRC on the Putting Science into Standards initiative.
[92] Evaluation, p. 34.
[93] Evaluation Study, p. 118.
[94] Judgment of 21 April 2026, *Nederlandse Voedsel- en Warenautoriteit and Others*, C-155/24, para. 38.
[95] T-581/24 *Public.Resource.Org, Inc. and Right to Know CLG v Commission;* T-53/25, *Public.Resource.Org and Right to Know v Commission*

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However, despite some improvements brought by the Standardisation Regulation, the ESS remains opaque as regards voting patterns, the position of different contributors as well as the interests represented in the development of hENs. The absence of systematic reporting on reconciling divergent views or the integration of public interest considerations further exacerbates this perception of opacity. Following a complaint from a non-governmental organisation, the European Ombudsman launched an inquiry in 2025[96] regarding the process for adopting hENs supporting the AI Act. The complainant was concerned that the Commission failed to take sufficient steps to ensure these standards are "*adopted in a transparent manner and that the process is subject to accountability*".

Driver 3.2: Reliance of the ESS on the sales of hENs

The challenges regarding the sustainability of the ESS are compounded by the impact of free access to hENs on **the financing of the CEN and CENELEC**. hENs, as any standard adopted by CEN and CENELEC, are sold by NSBs. While CEN and CENELEC and their member NSBs have diverse business models and funding sources (industry participation fees, public subsidies, revenues stemming from other activities such as accreditation or training), most of them rely on the sales of standards to generate revenues and to partly finance the standardisation process in their Member State.

Providing access to hENs through the readability portals has so far had **limited effects on the revenues of NSBs**. The number of requests for access to standards to the Commission surged since March 2024, with over 850 requests[97], out of which 80 % concerned hENs. In practice, out of the total portfolio of close to 3 100 hENs, access has been requested to 812 of them (26 % of the total). NSBs have mentioned that no visible decrease in their revenues was observed since March 2024[98]. Nevertheless, they had to incur investments to set up the platforms to provide free access to standards[99]. The limited impact until now can be explained by the restrictive conditions under which access is granted to hENs (read-only, on-demand), the lack of awareness that these standards are freely accessible and, more importantly, by the fact that the main users of hENs (businesses) prefer to pay for having full access to the hENs they need, often as part of commercial packages covering the entire portfolio offered by the NSBs.

However, NSBs are worried that the revenue stream stemming from their sales of hENs could decrease more significantly or even disappear as awareness of the possibility to consult hENs for free gains ground[100]. NSBs' legal forms and business models vary widely, as do their revenues and scope of activities (see Annex 8). The Commission has tried to identify, in close cooperation with the NSBs, **their dependency on the sales of hENs.** NSBs do not specifically track the sales of hENs, notably because many of them rely on a dual selling system based on subscriptions (yearly fee to access the entire standards database) and individual sales of standards[101]. Overall, it is estimated that the total sales of hENs by NSBs in the EU represents

[96] Case 1974/2025/MIK of 26.09.2025, *How the European Commission ensures transparency, inclusiveness and accountability in the adoption of hENs related to artificial intelligence*, European Ombudsman**.**
[97] The Commission received over 300 requests in 2024 from March onwards, over 450 requests in 2025 and over 100 in 2026 until April.
[98] Targeted interviews with NSBs.
[99] The Commission granted CEN and CENELEC close to EUR 5 million for the development of the platforms for access to standards, starting in April 2024 and expected to be completed by March 2029.
[100] Targeted interviews with NSBs.
[101] Targeted interviews with NSBs.

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around **EUR 30 million per year**, 15 % of the total sales of standards in the EU by the NSBs[102]. Given the diversity of business models of NSBs, their dependency on the sale of hENs varies across the EU, ranging from 1 % to 10 % for larger NSBs that are engaged in multiple activities to 20 % to 25 % for smaller NSBs more reliant on the sales of standards[103]. The magnitude of the shock from free access to hENs on NSBs' revenues thus depends heavily on the structure of each NSB and its ability to generate revenues beyond the sales of hENs.

2.2.4. Drivers related to Problem 4

Driver 4.1: More geo-economic competition from third countries

Data from the AFNOR international barometer[104] indicate **a rise in Asia's influence** in global TCs and working groups over the past decade. While Europe has traditionally dominated these activities and still maintains a strong presence, also through its cooperation programmes and free trade agreements, there has been a marked increase in participation from China, Japan and South Korea. For instance, China's involvement in ISO committees surged significantly: the number of TCs it led increased tenfold, while its participation in Working Groups grew by over 1 550 %[105] – a rise mostly at the expense of the UK and the US. By 2025, China participated in 778 TCs, ranking as the highest globally, and managed 90 secretariats, trailing only Germany and the US[106].

The US, historically driven by a corporate-led standardisation model, **maintains strong influence** through a mix of private-sector leadership and institutional representation: it holds about 50 % of voting rights in 11 out of 39 international SDOs and 67 % of the IEEE Standards Board membership, underlining its dominant position in core technical forums[107]. The US also appears to be adopting a proactive approach to counter China's growing prominence, aiming to safeguard its influence in critical technology sectors[108]. Despite this, the EU still leads in the overall number of TCs and working groups at ISO, but the shifting dynamics underscore China's expanding global influence and the US strategic interest in consolidating its position.

Driver 4.2: Lack of EU coordination

Recent research highlights that Europe is still a global standard maker, capable of providing a significant competitive advantage to EU industry[109]. This position relies on the strong connection between European NSBs and the global standardisation ecosystem, the quality of the ESS as well as the collective relative weight of NSBs from the EU in ISOs. However, **limited coordination between EU actors in ISOs,** across Member States, NSBs, the Commission and European experts, hampers this position. European industry, Member States

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[102] Data based on submission by NSBs from CEN/CENELEC for the year 2025. This is in line with the share of hENs the total portfolio of CEN/CENELEC (12 %). The share of hENs in new standards adopted by CEN/CENELEC is however increasing over time and represents on average 17 % since 2019.
[103] Annex 8 explains the methodology to estimate the sales of hENs by NSB belonging to CEN/CENELEC and details the results while respecting confidentiality of the information provided by the NSBs.
[104] AFNOR (2025), barometer international, Edition 2025.
[105] *The increasing dispute between USA and China over international standardization*, Padula and Pizetta.
[106] Standardisation with Chinese Characteristics?, CKN & Clingendael Report, July 2025.
[107] Securing Global Standards for Innovation and Growth, Shivakumar (2022). The IEEE Standards Board coordinates the development and revision of IEEE standards.
[108] The geopolitics of technology standards: historical context for US, EU and Chinese approaches, Blancato et al. (2024).
[109] Loyau and Bijlmakers, *Standards made in Europe for global use*, p. 1334, Innovation: The European Journal of Social Science Research, 2024.

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and ESOs have expressed concern about lost opportunities linked to insufficient coordination and sharing of information[110]. Before the creation of the HLF, there was no governance structure that allowed ESOs, NSBs and Member States to exchange information and positions on international standardisation matters, contrary to the discussions on European standardisation that take place in the Committee of Standards. The need for more active discussion on international standardisation matters has been reflected by the creation in 2026 within the HLF of a dedicated workstream on "Global standard setting and the EU position". While this represents a positive step forward, there is a general lack of awareness, training and experience sharing across EU experts taking part in international standardisation activities[111].

Last, there is no mechanism in the Standardisation Regulation to **coordinate the implementation of strategic autonomy objectives in standardisation** and to address the increased geopolitical and economic competition in international standardisation. Contrary to existing possibilities in EU-funded research projects[112], the Standardisation Regulation does not include any mechanism to ensure standardisation in support of Union legislation and policy is conducted by EU actors, nor the possibility to mandate ESOs to deviate from international standards if such standards would be contrary to EU values and interest.

2.3. How likely are the problems to persist?

The structural problems and problem drivers set out above will remain and **likely aggravate failing strong policy action from the EU**.

The difficulties of the ESS to deliver timely standards for legislation and policy purposes and the lack of alternative options for the Commission will continue in the future in the absence of any changes to the legal framework. The Standardisation Regulation, coupled with the case law of the CJEU, embeds the lengthy and complex process for delivering standards to the Commission. While increased cooperation with ESOs has led to improvements, the **average duration of the standardisation process is not expected to decrease** significantly if no changes are brought to the overall legal and administrative process. ESOs and the Commission launched the joint EC/ESO/EFTA task force running over 2021-2023 to find operational solutions to eliminate bottlenecks, maximise efficiency of processes on both sides, better anticipate future standardisation needs and clarify respective roles and interactions. The Task Force led to procedural improvements, notably the introduction of joint checklist for standardisation requests and assessment of standards as well as to better integration of IT tools. While this led to quality improvement and better cooperation between ESOs and the Commission, this was insufficient to have measurable impact on the time needed to deliver standards. Moreover, the Task Force identified 7 "fast-track" projects with the aim of ensuring delivery in 18 months. However, the initial assessment is that the 18-month target will not be met for most of these projects[113].

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[110] Targeted interviews with NSBs, ESOs and five EU industry organisations.
[111] Evaluation Study, p. 183.
[112] Notably Article 22(5) of the Horizon Europe Regulation establishing the Horizon Europe Programme for Research and Innovation, OJ L 170, 12.5.2021, pp. 1–68.
[113] The 7 projects identified focusses on high priority standards from a policy perspective, in the field of cyber-security, cyber resilience, trusted data and low carbon cement. The sensitivity and complexity of these technologies make it very difficult to reach a fast consensus among the experts on the content of the standards, despite enhanced cooperation with the Commission services introduced by the Task Force.

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The **insufficient participation** of SMEs, civil society organisations, public authorities and academia in standardisation remains a persistent issue, although the Standardisation Regulation has delivered clear improvements compared to the pre-2012 framework. However, these advances have primarily strengthened formal access, while effective and sustained participation continues to be constrained by structural factors.

The **uncertainty on the long-term sustainability of the ESS** is also likely to persist. First, several upcoming rulings by the CJEU are expected to shed light on whether the conditions under which access is granted to hENs comply with the principles of the rule of law, transparency, openness and good governance[114]. Second, while some NSBs have initiated steps to decrease their financial reliance on the sales of hENs, some NSBs remain dependent on this source of revenue to finance their standardisation activities and have limited opportunities to identify alternative revenue sources[115]. The uncertainty regarding the financial sustainability of the ESS also increases the risk that ESOs' incentives to engage in the public/private partnership for EU standardisation would decrease, thereby endangering the sustainability of the ESS in the long run as well as the ability of the Union to rely on standards to support legislation and policy.

Last, the current trend of **increasing international competition in the standardisation process is likely to amplify** as main actors plan to continue investing in standardisation (China, the US) and other actors plan to increase their investments (*e.g.* India). The EU risks further losing influence in the international standardisation system, impeding its competitiveness and the ability to support its values in global standardisation systems.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The Standardisation Regulation's legal basis is **Article 114 of the Treaty on the Functioning of the European Union** for the adoption of measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

3.2. Subsidiarity: Necessity of EU action

EU-level action is necessary to ensure an efficient and harmonised ESS that contributes to the functioning and competitiveness of the internal market. The EU faces global competition from other major economic blocs along with various other challenges and needs to ensure that the internal market remains competitive, accessible, innovative and continues to promote a level playing field.

Considering the role standards play in guaranteeing the interoperability and safety of products and services within the EU internal market, **improving the ESS responsible for developing European standards at EU level is necessary.** European standards are common across all Members States and the EEA and significantly decrease the barriers within the internal market as they foster inter-operability, value-chain integration as well as consumer confidence across

[114] T-581/24 *Public.Resource.Org, Inc. and Right to Know CLG v Commission,* T-53/25, *Public.Resource.Org and Right to Know v Commission*.
[115] Targeted interviews with NSBs.

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Member States. **Moreover, the problems affecting the functioning of the ESS are of common EU nature** and shared by all Member States.

A cost-effective and timely standardisation system to support Union policy and legislation is unattainable by Member States acting alone. In the absence of EU level action, the identified problems would persist, as Member States are unable to enact the appropriate measures to foster a resilient ESS that supports the internal market and maintains EU global competitiveness. If no such action is taken, Member States might find alternative pathways to foster national standardisation outside of the ESS. Fragmentation in approaches by different national and sectoral actors would erect barriers to entry and risk creating inequalities within the internal market. Last, the measures concern actors operating at EU level, therefore national measures would not be able to coherently enact the necessary changes.

3.3. Subsidiarity: Added value of EU action

Action at EU level to tackle the identified problems would be conducive to a more harmonised, effective, efficient and coherent outcome across the internal market in support of the broader strategic objectives of the Union. It would **address the shortcomings in the current ESS framework in a comprehensive manner**.

The Evaluation shows that the added value of the ESS lies in its contribution to increased intra- and extra-EU trade, reduced compliance costs, increased influence on international standardisation and improved inclusiveness in the development of standards, compared to national systems. Standards are essential to the effective functioning of the internal market and to EU competitiveness, technological sovereignty and ability to conduct the green and digital transitions. EU action to improve the functioning of the ESS and address the problems identified would improve the functioning of the internal market through faster and higher quality hENs and create economies of scale for Member States, notably in ensuring the inclusiveness of the standardisation process and in consolidating the EU's influence in international standardisation.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

Three general policy objectives have been identified for the revision of the Standardisation Regulation to address the problems identified above, in line with the current objectives of the Regulation as well as with the Union policy objectives.

Fostering global EU competitiveness and technological sovereignty

The ESS supports innovation and market access by providing a uniform technical framework that fosters the adoption of innovation by market operators, ensures interoperability and facilitates trade, allowing businesses to integrate new products into global supply chains without facing unnecessary technical barriers while ensuring consumer trust in the products and services. It can help EU technologies achieve first-mover advantages in global markets by embedding EU-derived technical rules into international standards[116]. This is only possible, however, if EU standardisation processes are sufficiently agile, inclusive and strategically

[116] For example, China has been adopting several voluntary and mandatory national battery standards to support its rapidly expanding industry – see analysis from SESEC, China Introduces Mandatory Battery and Vehicle Standards with Implications for Foreign Stakeholders.

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coordinated. Standards also prevent lock-in into proprietary solutions, often owned by non-EU firms. This reduces barriers to export and allows European firms, including SMEs, to compete more effectively against non-EU firms in strategic sectors. hENs also reduce dependency on third-country technical regimes, thereby contributing to technological sovereignty, a central thread of the Compass's ambition to close the innovation gap and reduce external dependencies.

Ensuring the better functioning of the EU internal market

hENs eliminate technical barriers within the internal market by ensuring that products, services and systems meeting these standards can circulate freely across all 27 Member States while safeguarding a high level of consumer protection by embedding health and safety requirements. This efficiency directly supports the Compass's goal of removing barriers and making it easier for companies, especially those operating across borders, to scale without facing divergent national technical requirements, which requires the timely availability, legal robustness and consistent application of hENs across Member States.

Reducing regulatory costs for EU businesses, in particular SMEs

hENs are a **key simplification tool for businesses** as they clarify technical expectations for compliance with EU legislation. They reduce the need for bespoke compliance solutions and lower the cost and complexity of conformity assessments. This aligns with the Compass's target of cutting regulatory costs, in particular for SMEs. Inclusive standardisation processes leading to quality hENs can reduce legal uncertainty and the need for multiple national assessments.

4.2. Specific objectives

To achieve these objectives, the revision of the Regulation should address the problems and their drivers identified in section 2. Three specific objectives have been identified.

Specific Objective 1: Improving the responsiveness of the ESS

This first specific objective focuses on the performance of the ESS. Improving its "responsiveness" aims at addressing the persistently slow and uneven delivery of hENs, by making the system faster, simpler and more agile. From an operational perspective, this means (i) ensuring standards are delivered **on time** to support EU legislation; (ii) **increasing the overall speed of standardisation** in support of EU legislation and policy; (iii) increasing the **flexibility of the ESS** to increase reactivity and avoid bottlenecks, and (iv) increasing the **quality of standards,** closer to the state of the art.

Specific Objective 2: Ensuring the a financially viable and inclusive ESS

The second specific objective focuses on the functioning of the system, ensuring that relevant stakeholders actively participate in the process and that rules for access to standards with a legal effect are stable and predictable and allow for the ESS to continue delivering standards for Union legislation and policy purpose. From an operational perspective, this means (i) increasing the **incentives for SMEs to participate** in the ESS, (ii) improving the **inclusiveness of the ESS for civil society stakeholders**, (iii) ensuring continuous incentives for **industry and experts to participate** in standardisation, (iv) ensuring the **financial sustainability of the ESS** and (v) ensuring **free access to standards** and providing public information on standards-development processes. Specific Objective 2 thus aims to address two problems identified in the Evaluation and in the section 2 of the IA: the lack of balanced stakeholder participation and uncertainty regarding the sustainability of the ESS linked to the new requirements for free access to standards. The two problems are linked because they both affect the financial viability

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of the NSBs. Legal requirements as regards free access to hENs impact the revenues of NSBs and the financial incentives of ESOs and NSBs to develop and deliver hENs. The financial sustainability of the NSBs is also closely linked to its inclusiveness as fostering stakeholder participation in the standardisation process is important part of the costs of NSBs and the functioning of the ESS. The direct link between financial sustainability and inclusiveness is also highlighted by the Union's financial support to the ESS that is directed either at financial sustainability (financing of ESOs' operating grants) or at inclusiveness (financing of Annex III organisations and of industry participation in the standardisation process).

Specific Objective 3: Consolidating the EU influence in international standardisation

The third specific objective aims at consolidating the EU position in international standardisation, in light of increasing geopolitical strategic competition and of the importance of international standards for the competitiveness of EU industry. From an operational perspective, this means (i) improving **coordination** and participation of EU actors in international standardisation, and (ii) fostering the **ability of the EU to maintain its strategic autonomy** in standardisation.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

The baseline scenario is based on the existing Standardisation Regulation. It is a "no-policy-change" scenario: it assumes that non-legislative changes and relevant legislative initiatives either adopted or proposed are implemented, *i.e.* the Omnibus IV (expected adoption in 2026). A description of the current governance and resources in the Commission for European standardisation is provided in Annex 12. No improvement to the situation identified in Section 2 is expected, apart from three measures described below, impacting responsiveness and sustainability of the ESS.

ESO-driven digitalisation of the ESS

While the ESS has traditionally relied on the production and use of human-readable, document-based standards, ESOs are currently working on **digitalising both the standardisation process**, through the Online Standard Development project (OSD) and **its deliverables**, through the SMART (Standard Machine Applicable Readable Transferable) project[117]. The objective is to move from document-centric to data-centric standards[118]. Expected benefits include faster collaboration, automation and iteration, reducing the time needed to resolve comments[119], improved quality through the facilitation of knowledge transfer between research projects and standardisation bodies, reduced human error, and simplified exchanges and quality checks[120]. Moreover, digitalisation is expected to foster the inclusiveness of the standardisation process by decreasing the costs to participate, notably cutting travel costs to take part physically in TC meetings. The SMART project of CEN/CENELEC will also enable to develop value-added services based on standards, such as. training, compliance support, process integration

[117] Evaluation Study, p. 111.
[118] Standards will become machine readable in a format that provides structured content that can be recognised and validated by software.
[119] Workshop with NSBs.
[120] OSD could notably reduce manual extraction, decrease interpretation errors, improved traceability of requirements for conformity assessment and enable earlier detection of non-compliance.

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advice on how to apply standards or services to integrate standards in the activity of customers[121].

One of the main effects of the digitalisation process engaged by the ESOs will be to speed up standardisation. CEN/CENELEC estimate development time could be cut by 25-50 %, reaching 18-24 months versus the current 3-year average[122]. Considering that these projects are on-going, the conservative lower end (-25 %) is retained for the baseline[123]. The targeted survey to companies and industry associations confirms the potential of digitalisation: 82 % of respondents saw digitalisation as contributing to the responsiveness of the ESS[124].

The ambitious digitalisation of the ESS will require significant investments, mostly borne by the ESOs and the NSBs. Through action grants under the Single Market Programme (SMP), the Commission provided over EUR 1.1 million to finance the SMART and OSD projects until end 2027[125], and is in the process of financing a similar project for ETSI for EUR 0.4 million[126]. The Commission also provided EUR 1.7 million[127] to improve the ESOs' IT systems and ensure their interoperability with the eNorm system. The adjustment **costs for the Commission itself will be limited** since investments have already been made to articulate the IT systems (the costs of the eNorm system are EUR 1.0 million per year over 2025-2027).

Common specifications under Omnibus IV

The Omnibus IV proposal extends the possibility for the Commission to adopt CS to 13 Directives and 4 Regulations of the NLF[128]. With this proposal, 95 % of hENs would support a legislation that includes the possibility to adopt CS, up from 50 % – see Annex 9. However, effects will likely remain limited, as CS do not increase the speed of standardisation as they can only be adopted when the ESOs are late or fail to deliver. CS have also until now very rarely been used as a policy tool[129]. The main benefit is to increase legal certainty by ensuring market operators can benefit from presumption of conformity even when the standardisation process is blocked. It would in addition increase the incentives for ESOs and industry to deliver hENs as the OPC for this IA shows that CS are not among the preferred solutions of stakeholders when there are no hENs at the time of applicability of the legislation[130].

Developing and adopting CS will incur additional administrative costs on the Commission. It will have the responsibility to mobilise the relevant expertise to draft the CS,

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[121] *The business-oriented benefit of smart standards in standard application processes*, 2024, DIN and DKE. Information retrieved from targeted interviews to NSBs.
[122] Impact Assessment study, p. 32.
[123] This assumption is reinforced by the results of the OPC, in which stakeholders identified risks in shifting work to online platforms as this could disrupt the traditional way experts collaborate.
[124] Targeted survey to companies and industry associations (203 respondents out of 247).
[125] European Commission - Financial Transparency System.
[126] The grant agreement supporting the ETSI project to start the process towards the implementation of smart standards is expected to be signed in 2026 and shall last until 2028.
[127] EUR 1.5 million for CEN/CENELEC and EUR 0.25 million for ETSI. European Commission - Financial Transparency System.
[128] See Annex 9 for more information about changes introduced by the Omnibus IV proposal regarding CS.
[129] In recent years, the process to Commission adopted CS in the framework of the Medical Device and In Vitro Medical Device Directives. CS were adopted after 3 to 5 years, showing that the drafting time is not shortened compared to hEN.
[130] Respondents to the OPC preferred using previous editions of standards (26 %, 83 out of 320), technical specifications developed by ESOs (23%, 74 out of 320) or international standards (17 %, 54 out of 320) ahead of CS (14 %, 45 out of 320). However, none of these options provides presumption of conformity.

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notably through dedicated expert groups, and to assess if the CS accurately reflect essential requirements. The impact would be proportional to the number of CS adopted as there are limited economies of scale due to their technical nature. The industry would play a similar role in developing CS as in the standardisation process and bear most of the costs by providing resources and expertise.

Access to standards through readability platforms

The Commission, CEN-CENELEC and NSBs have cooperated to provide access to hENs free of charge by creating European[131] and national readability platforms[132] that give read-only access to hENs based on individual requests[133]. This has led to **improved access to hENs for industry, SMEs, and the general public**, with **limited direct effect on NSBs' revenues.** Although they have not been in place for a sufficient amount of time (2 years) to draw solid conclusions, only 3 of 17 NSBs reported a meaningful use of their platform in terms of access and loss of revenues[134]. The targeted survey with industry organisations and companies indicated a very low awareness of such platforms as more than 82 % of respondents were unaware of or rarely used the platform[135]. The limited impact on NSBs' sales is also explained by the fact that the price of hENs is not perceived as a barrier[136]. Thus, **it is unlikely that the current conditions of access to hENs affect NSBs revenues**[137].

The set-up of the readability platforms required significant initial investment from the Commission, leveraging existing tools such as the EASE platform for access to documents and the eNorm platform. The Commission also supported the financing of the ESOs and NSBs platforms with a EUR 5.0 million action grant, running until end 2029[138].

5.2. Description of the policy options

Three policy options are considered, while another one was discarded at an early stage.

Policy Option 1: *a modernised ESOs' monopoly* **retains the core structure of the current ESS**, with ESOs remaining the only standardisation organisations entitled to receive requests from the Commission. Targeted improvements are introduced to enhance the responsiveness of the ESS, ensure its sustainability and foster international influence. Policy Option 2: *an ESS centred on ESOs with new flexibilities* retains ESOs as the cornerstone of the ESS but **introduces two key innovations**: alternative routes for the Commission to request standards and free and unrestricted access to hENs. Last, Policy Option 3: *an open ESS managed by the Commission* marks a **fundamental departure from the current ESS,** replacing the ESOs'

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[131] eNorm Platform – Access to harmonised standards.
[132] CEN/CENELEC has set up a portal that gives access to all the available national readability platforms: https://harmonized.standards.eu/.
[133] hENs are disclosed according under Regulation (EC) No 1049/2001 on Access to Documents. The platforms also grant access to standards directly referenced in Union legislation with a legal effect.
[134] Targeted interviews with NSBs/NCs/NSOs. Impact for these NSBs was a 6 % decrease in sales of hENs.
[135] Targeted survey with industry organisations and companies. 29 % (72 respondents out of 247) were unaware, 28 % consulted rarely (68 out of 247) and 25 % never (62 out of 247).
[136] Targeted survey with industry organisations and companies. 5 SMEs respondents out of 108 declared to have requested access when a standard was considered too expensive.
[137] The impact on NSBs' sales could gradually increase with increased awareness of the readability platforms. However, standards are purchased once and not every year, hence the impact of access on revenues is not cumulative. In the baseline, a no-revenue loss is assumed.
[138] European Commission - Financial Transparency System

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monopoly with a publicly managed system, in which the Commission can choose the most relevant SDO for each request and publishes hENs in the OJEU.

Policy Option 1: Modernised ESOs' monopoly

To address Objective 1 (improving responsiveness of the ESS), a first measure is to foster the **integration of publicly available specifications from other SDOs** into the ESS (*Measure 1.1*). ESOs would be requested specifically in standardisation requests to incorporate high-quality technical standards or standardisation deliverables developed by other SDOs. ESOs are already developing this possibility under the PAS (Publicly Available Specification) process, for which they enter into structural agreements with other SDOs on the integration of their standards or technical specifications into their own standardisation process. This approach would enable ESOs to better leverage technical expertise where it is available and closer to the state of the art, thereby speeding up the standardisation process for critical technologies like AI, cybersecurity, or clean technologies. An additional measure to improve responsiveness includes **the consolidation of the use of CS by the Commission into the Standardisation Regulation** (*Measure 1.2*). This will streamline the conditions of use and the process for the Commission to develop CS when ESOs fail to deliver hENs on time or meet expected quality levels, including by clarifying the interaction between CS and hENs and allowing the Commission to build on existing ESO work to develop CS while ESOs continue to develop a hEN to replace the CS. The option also introduces a **presumption of conformity on a temporary basis for standardisation deliverables other than standards** (*Measure 1.3*). This measure enables faster market access where hENs are still under development, but essential requirements can be covered by a standardisation deliverable that has not yet reached the full consensus stage[139]. The presumption of conformity would be time-limited and subject to the continuation of the standardisation process with the objective of transforming the standardisation deliverable into a hEN. To foster transparency and accountability within the ESS, this measure would improve **strategic planning of standardisation** by improving the anticipation of standardisation needs to support upcoming policies and legislation (*Measure 1.4*). This would notably take place through a better articulation of short- and long-term standardisation needs in the Annual Union Work Programme on European standardisation (AUWP) and through the introduction of KPIs on the Commission's and ESOs' performance, including on timeliness, quality and stakeholder participation. The introduction of deadlines for the Commission and ESOs would also further increase transparency about the process, better planning and reduce unnecessary delays. This will be complemented by the **simplification of the legal process to deliver hENs** (*Measure 1.5*). Binding deadlines at key steps in the process would be introduced to improve predictability. The measure would also accelerate the decision-making process by **removing the requirement for comitology procedure** for adopting standardisation requests, by simplifying the process for formal objections to published hENs and by mandating the submission of digital hENs and fostering their development using online tools. It would also introduce a collective decision mechanism on formal objections to hENs to increase legal certainty and reduce the average duration of the formal objection process.

For Objective 2 (ensuring a financially viable and inclusive ESS), this option retains the current system **of readability platforms** providing read-only access to hENs on request. This option extends the **requirements in Article 6** of the Standardisation Regulation applying to access to

[139] Such standardisation deliverables could be adopted by ESOs faster through less procedural steps and even in case no full consensus has been reached on all technical aspects, as long as a majority of stakeholders and NSBs agree, similar to the process currently used for technical specifications. The standardisation deliverable would still meet requirements of inclusiveness and transparency and cover the essential requirements.

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SMEs to **all civil society organisations** to enhance their participation in the standardisation process (*Measure 1.6)*. These stricter requirements for NSBs would include financial incentives, such as free access to draft and adopted standards or special rates for standardisation activities, as well as procedural incentives, such as identifying relevant projects and allowing participation without membership. This option also includes measures to increase **incentives to foster experts' participation in standardisation,** in particular targeted at the R&I community, by increasing awareness of experts on the standardisation process and by better coordinating public financial support (*Measure 1.7*). This would notably include greater awareness of standardisation in research and academic curricula, recognition of pre-norms, closer links between research results and standards development, free access for researchers to relevant standards and draft standards, and awareness-raising also for industry experts, in particular SMEs. Last, the option introduces **transparency registers** to allow the public identification of interests represented and active in the standardisation process for hENs (*Measure 1.8)*. ESOs would be required to set up online transparency registers for this purpose.

For Objective 3 (consolidating the EU's influence in international standardisation), this option introduces **an EU-Member States coordination mechanism** (*Measure 1.9*) to improve sharing of information on international standardisation and foster more coherence of NSBs' and EU experts' positions. This mechanism would include regular coordination meetings chaired by the Commission to exchange on the EU perspective on key developments in ISO, IEC or ITU, while NSBs would retain the independence of their vote. It would also include an information-sharing mechanism between the Commission, ESOs and NSBs. The option would also clarify **the possibility to restrict participation in ESO TCs to EU/EEA actors** in specific and targeted cases involving sensitive sovereignty or strategic areas, such as defence or critical technologies (*Measure 1.10*). Any such clarification would need to remain consistent with WTO rules. The option otherwise maintains the baseline approach to international cooperation, based on the "international first" principle.

Policy Option 2: An ESS centred on ESOs with new flexibility

To address Objective 1 (improving the responsiveness of the ESS), this option retains measures 1.1 to 1.5 introduced in Option 1. It adds **the possibility for the Commission to directly send standardisation requests to alternative SDOs other than the ESOs** (*Measure 2.1*). The Commission could address requests to other SDOs under specific conditions, such as when ESOs decline a request, fail to meet deadlines or quality expectations, or when the Commission considers that an alternative SDOs would be objectively more relevant after having consulted the ESOs. To ensure sufficient quality of the provided standards and notably the inclusiveness of the process conducted by alternative SDOs, the Commission would only be authorised to rely on vetted SDOs that respect the WTO principles for standardisation, can ensure an inclusive standardisation process and adequately represent EU interests. These vetted organisations would have to comply with criteria inspired by the current Annex II of the Standardisation Regulation. This measure would not eliminate the ESOs' central role in the ESS, as they would be consulted first on their ability to deliver hENs. As a significant departure from current practice, standardisation requests to alternative SDOs would be consulted and validated by Member States through the Comitology procedure, to ensure all national interests are taken into account as alternative SDOs would not ensure the same formal representation of national interests currently enabled by ESOs.

This option also introduces **a Chief Standardisation Officer (CSO) in the Commission, supported by an EU Expert Centre** (*Measure 2.2*). The Centre would be tasked with coordinating the expertise on standardisation in the Commission and with identifying and

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managing standardisation requests to alternative SDOs. It would also help ensure that such requests are aligned with EU priorities, implemented in a consistent manner, while supporting the mobilisation of experts, the elaboration of common specifications and the coordination of EU experts in international standardisation.

For Objective 2 (ensuring a financially viable and inclusive ESS), this option introduces **free and unrestricted access to hENs** (*Measure 2.3*). Access would be provided via a central repository, which could be managed by ESOs, and / or by the Commission[140], through an online portal. Unlike Option 1, which only provides on-demand, read-only access upon request, this option allows unrestricted access for any user. In practice, this would require a central repository where users could consult hENs free of charge, under general and non-discriminatory conditions and without having to identify themselves, with searchable consultation features and potentially download features. This option introduces **binding requirements for NSBs to foster the participation of SMEs and civil society representatives**, based on the current measures of Article 6 of the Standardisation Regulation (*Measure 2.4*). This would include financial incentives at national level, such as reduced fees, as well as measures facilitating effective participation. The option also retains measures 1.7 and 1.8.

For Objective 3 (consolidating the EU's influence in international standardisation), in addition to measure 1.9 and 1.10, this option introduces the possibility to **derogate from the "international first" principle in defined cases[141]** (*Measure 2.5*). This would ensure the possibility to adopt hENs that reflect EU values and interests in parallel to existing international standards in strategic or sovereignty-sensitive areas. In such cases, the Commission could issue requests requiring the EU side to lead under the Vienna/Frankfurt framework[142] or, alternatively, to pursue European standardisation separately from international standardisation, with limitation of participation to EU-based entities where needed.

Policy option 3: An open ESS managed by the Commission

To address Objective 1 (improving the responsiveness of the ESS), this option retains measures 1.1 to 1.5. This option **eliminates the ESOs' exclusive right to receive standardisation requests** by allowing the Commission to submit standardisation requests to any SDO (*Measure 3.1*). Unlike Option 2, which retains a sequential preference for ESOs, this option grants the Commission full discretion to select SDOs based solely on merit, without embedded preferences or prior obligations. This could be implemented either through an expanded Annex I, listing vetted SDOs meeting minimum requirements for trust, quality and inclusiveness, or through a fully open competitive model in which requests could be addressed to any SDO, with case-specific requirements set in the standardisation request.

To address Objective 2 (ensuring a financially viable and inclusive ESS), this option ensures public access to hENs **by publishing them in OJEU** (*Measure 3.3*). This approach would make

[140] Free and unrestricted access would also be granted to hENs stemming from alternative SDOs; this could be done either through the ESOs/NSBs platform or through the Commission's platform.
[141] Derogations from the primacy of international standards are in principle justifiable under the WTO TBT Agreement and EU FTAs, in cases where an international standard or relevant parts of it would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.
[142] The Vienna Agreement and Frankfurt Agreement are framework accords designed to harmonize international standards with European standards. Their primary purpose is to avoid duplicate work, pool technical expertise, and streamline global trade by allowing a single standard to be approved simultaneously at both levels. See: https://single-market-economy.ec.europa.eu/single-market/goods/european-standards/standardisation-policy/international-activities_en.

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hENs publicly available in their entirety in all official languages, placing them in the public domain. This would replace the current practice of publishing only references to hENs in the OJEU and could have budgetary implications if the Commission were to compensate SDOs for standards development. To ensure inclusiveness, this option **introduces mandatory participation and inclusiveness requirements for SDOs to be eligible to receive Commission requests** (*Measure 3.4*). These requirements could include compulsory lower fees for SMEs, academia and civil society. Additional *ad hoc* participation requirements could also be inserted in individual standardisation requests.

For Objective 3 (consolidating the EU's influence in international standardisation), this option retains measures introduced in Option 1 and 2 (*Measures 1.9 and 1.10*) but also provides the possibility for the Commission to exercise full **discretion on whether to align with the "international first" principle** or prioritise EU-specific standards in strategic sectors (*Measure 3.5*). Since this option introduces the possibility to choose on a case-by-case basis the SDOs requested to deliver a hEN, it would allow the EU to align standards with its priorities, values, and interests for each standardisation request, but could also widen the gap between European and international standards.

To support the implementation of all measures, this option establishes an **EU Standardisation Office** (*Measure 3.2*), centralising the Commission's expertise on standardisation. The Office would identify the most appropriate SDO for each standardisation request, ensure effective access and inclusiveness of the standardisation process and coordinate EU positions in global fora to strengthen global influence. It would also oversee possible compensation for standards development or acquisition and would regroup Commission resources currently engaged in implementing the Standardisation Regulation under a more centralised governance model.

The measures introduced in each option are listed in Figure 3 and described in Annex 10. Options 1 and 2, although presenting important differences, build on one another and explore various improvements to the current ESS without fundamentally modifying the way it functions. The policy measures are grouped for coherence and level of ambition, with a gradual approach from relatively lighter regulatory changes in Option 1 to more wide-ranging changes in Option 2. Option 3 marks a **more pronounced departure from both the baseline scenario** and the other two policy options, as it explores a significant change in the way the ESS is both organised and managed.

Figure 3: Overview of policy measures and options

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	Option 1: ESS centred on ESOs	Option 2: ESS centred on ESOs	Option 3: Open ESS
Objective 1: Increasing the responsiveness of the ESS	**1.1 Integration of standards from other SDOs by ESOs** **1.2 Common specifications as fall-back to hENs** **1.3 Temporary Presumption of Conformity** **1.4 Improved strategic planning and accountability** **1.5 Simplification and digitalisation**	1.1 Integration of standards from other SDOs by ESOs 1.2 Common specifications as fall-back to hENs 1.3 Temporary Presumption of Conformity 1.4 Improved strategic planning and accountability 1.5 Simplification and digitalisation 2.1 **Flexibility to address requests to alternative SDOs** 2.2 **EU Expert Centre led by CSO**	1.1 Integration of standards from other SDOs by ESOs 1.2 Common specifications as fall-back to hENs 1.3 Temporary Presumption of Conformity 1.4 Improved strategic planning and accountability 1.5 Simplification and digitalisation 3.1 **Open selection of SDOs for requests** 3.2 **EU Standardisation Office**
Objective 2: Ensuring a legally viable and inclusive ESS	0.5 Readability platforms **1.6 Strengthened obligations on NSBs towards inclusion of civil society** **1.7 Increased incentives to foster experts' participation** **1.8 Transparency requirements on participation to standardisation**	2.3 **Free and unrestricted access from central repository** 2.4 **Binding requirements for NSBs on inclusion of SMEs and civil society** 1.7 Increased incentives to foster experts' participation 1.8 Transparency requirements on participation to standardisation	3.3 **Publication of of hEN in OJEU** 3.4 **Fostering inclusiveness in all SDOs** 1.7 Increased incentives to foster experts' participation 1.8 Transparency requirements on participation to standardisation
Objective 3: Consolidating EU international influence	**1.9 Improved EU coordination on positions and participation** **1.10 Possibility to restrict participation to standardisation to EU/EEA**	1.9 Improved EU coordination on positions and participation 1.10 Possibility to restrict participation to standardisation to EU/EEA 2.5 **Possibility to derogate from International First principle**	1.9 Improved EU coordination on positions and participation 1.10 Possibility to restrict participation to standardisation to EU/EEA 3.5 **End of automatic international first principle**

5.3. Option discarded at an early stage

During the initial scoping phase, the option to **eliminate the presumption of conformity provided by hENs** was considered to combine the need to comply with the requirements to provide free access to standards with the preservation of NSBs' business models. The rationale was that, without presumption of conformity, hENs would lose their legal effect, thereby resolving conflicts regarding free public access to hENs. However, this option was discarded at an early stage due to severe drawbacks that outweigh its benefits. The presumption of conformity is a cornerstone of the EU's NLF, serving as a critical tool for harmonisation in the internal market, facilitating trade and innovation. The option would have led to:

- **Increased fragmentation of the internal market**: manufacturers could face divergent national interpretations of essential requirements, increasing technical barriers to trade.
- **Loss of legal certainty**: businesses would lose a reliable, EU-wide compliance pathway, increasing regulatory uncertainty and compliance costs that would have to be undertaken at national level (*e.g.*, duplicate testing for each Member State).
- **Weakened EU competitiveness**: it would have decreased industry's incentives to participate in standardisation to support Union legislation, thereby impeding the EU's ability to effectively enforce key legislation for the EU's competitiveness.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

6.1. Methodology

As highlighted in the Evaluation, assessing the effects of the Standardisation Regulation is a **complex exercise** since it supports the implementation of a wide range of sectoral legislation. Both the use and actual benefits of hENs differ across sectoral legislation, depending on the requirements with which hENs ensure compliance. There are also few **economic literature and conceptual frameworks** on the contribution of hENs to the functioning of the internal market, competitiveness and technological sovereignty. Last, there is a **scarcity of data** from

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the industry on the costs and benefits of their participation in standardisation, as well as from the NSBs on their business models as independent organisations. The Impact Assessment introduces two main innovations (see Annex 4):

- It introduces a quantitative analysis of the direct effects of policy options by **estimating the average savings in compliance costs** due to the availability of hENs.
- It estimates the **financial impact of policy measures on the expected revenue flows of ESOs and NSBs** to assess the financial sustainability of the ESS.

Economic impacts

Policy measures are assessed based on their impact on **the speed and timeliness** of the standardisation process. Benefits for businesses are then estimated based on their **savings in compliance costs**, as the earlier availability of hENs decrease conformity assessment costs[143]. The efficiency of policy measure is assessed across all relevant stakeholders. As many policy measures transfer costs from one actor to the other, the analysis focusses on qualifying how these transfers affect their incentives to support the specific objectives. The costs for the Commission, in particular stemming from additional resources necessary to implement the policy options, are detailed[144]. The **macro-economic impacts** of options are also assessed.

Social and environmental impacts

The assessment does not consider **the environmental and social impacts of each measure**. As a horizontal initiative supporting sectoral products and services legislation, the policy measures have negligeable direct environmental and social impacts[145]. hENs can make an important contribution to the EU environmental, social or societal objectives, such as for instance improving accessibility, safety and inclusivity of EU products and services. However, such effects directly depend on the sectoral legislation and on the definition of essential requirements and should be assessed in that context. A more effective standardisation system would enhance the ability of sectoral legislation to achieve its environmental and social objectives[146].

6.2. Impacts on Specific Objective 1: increasing the responsiveness of the ESS

The quantitative assessment of impacts under Specific Objective 1 (increasing the responsiveness of the ESS) is in particular affected by the diversity of sectors concerned and the difficulty to use sector-specific data due to data scarcity. The impacts are therefore estimated relying on a mix of quantitative and qualitative data, including surveys, interviews, workshops, case studies and expert validation. In particular, the quantification of "responsiveness" requires assumptions both on the time reduction generated by each measure and on the translation of earlier availability of hENs into compliance cost savings for businesses. These relationships are

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[143] The assessment relies on the estimate of the average cost saving of EUR 3 700 per standard used for conformity assessment identified in the Evaluation. The figure provided an estimated average across all sectors. Conformity assessment costs may however vary widely depending on the complexity and the risk of the product, ranging from as low as EUR 500 for a toy to over EUR 600 000 for complex medical devices.

[144] The assessment of additional resources for the Commission is indicative as the revision of the Standardisation Regulation will enter into force after 2028. All impact on financial resources of the Commission will take place under the next Multi-annual Financial Framework.

[145] One exception is the digitalisation of the ESS of the Baseline scenario. Digitalisation has a direct positive effect on CO2 emissions as it reduces the travels required from experts to take part to TCs. These effects occur similarly in all policy options and are thus not discriminating for identifying the preferred option.

[146] Evaluation, p. 39.

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not directly observable in all sectors and are therefore estimated using conservative assumptions, triangulated where possible with Evaluation findings, desk research, benchmarking against standard-setting organisations and international practices, and validation with experts. The resulting figures should be interpreted as indicative orders of magnitude primarily supporting the comparison of options.

6.2.1. Policy Option 1: Modernised ESO monopoly

Measure 1.1: Integration of standards from other SDOs by ESOs

The facilitation of the integration of publicly available specifications from other SDOs into the standardisation process of ESOs could make **a significant contribution to cutting the time necessary for the delivery phase.** While the actual time reduction would depend on each specific case, and on the actual availability of technical specifications developed by SDOs, it can be estimated to decrease **the delivery time to 12 months on average**[147]. This estimation is based on the current practice of ESOs to develop Workshop Agreements, a fast-track standardisation process developed in a temporary setting with direct participation of all interested stakeholders that can deliver in 10 to 12 months[148]. The total yearly savings in compliance costs for businesses linked to such reduced duration to deliver hENs are estimated at **EUR 23.5 million overall**[149]. This assumes that this measure would mostly apply to sectors where alternative SDOs are active and ahead of the state of the art compared to ESOs[150].

The measure is considered effective by stakeholders: **75 % of industry respondents (185 out of 247) considered the use of existing standards from alternative SDOs to accelerate the standardisation process**[151] and 57 % (140 out of 247) viewed the use of existing standards as a benefit[152]. ESOs are also supporting this measure and actively engaging with other SDOs to better integrate their specifications[153].

Beyond the direct impacts on hENs' development time, the measure would also contribute to **increase the quality and diffusion of hENs**, by ensuring they rely on state-of-the art discussions held in specialised fora, while benefitting from the inclusive and quality development process from the ESOs. The measure would also **increase the incentives of the industry and experts**, in particular in highly technological areas, to engage in the standardisation process in specialised SDOs, knowing that this investment would in turn feed the development of hENs, contributing to limiting duplication of investments.

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[147] A good example of such potential time gains is given by the case study 3 on electric vehicle charging infrastructure, See Annex 15.
[148] Impact assessment study, p. 40.
[149] This figure is obtained by multiplying the expected time reduction multiplied by the reduction in conformity assessment cost and the number of conformity assessments and companies in scope. The methodology is set out in Annex 4.
[150] The measure is assumed to apply to 10 % of new requested hENs as the upcoming hENs in the digital and new technology sectors represent 10 % of all expected standards.
[151] Targeted survey to industry organisations and companies.
[152] Targeted survey to industry organisations and companies. Case study 3 on electric vehicle charging infrastructure highlight a concrete example of how ESOs using existing standards and technical specifications from other SDOs could improve standardisation outcomes. See Annex 15.
[153] Targeted interviews with ESOs.

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Limited additional costs for the ESS are expected from the measure[154]. ESOs may incur some adjustment costs linked to engaging and formalising agreements with other SDOs, which could lead to some compensation to use technical specifications. These costs are hard to assess and many SDOs have indicated the possibility to agree to agreements without compensation[155]. This could also require additional human resources for the ESOs to identify, engage and integrate deliverables from other SDOs in the current standardisation development process. The Commission will incur limited additional costs as the measure would not change the assessment process but would require more active monitoring of the activities of other SDOs to identify relevant technical specifications, estimated at 1 additional FTE[156].

Measure 1.2: Common specifications as fall-back to hENs

This measure expands **the scope of legislation covered by CS** by ensuring that all legislation providing presumption of conformity through hENs can also rely on CS adopted by the Commission when the standardisation process fails. However, in practice, **only a few pieces of legislation would be added, covering 5 % of the current portfolio of hENs**[157]. Looking ahead, only 24 of 767 hENs planned for the next 5 years (3.2 %) concern legislation not yet covered by CS[158], confirming the measure's limited direct impact and negligible cost implications. The measure can however indirectly contribute to the responsiveness of the ESS by streamlining the possible use of CS and ensuring they are a credible fall-back to hEN, as mentioned in Section 5.

Measure 1.3: Temporary presumption of conformity

Introducing temporary presumption of conformity to standardisation deliverables other than hENs would significantly **decrease the delivery phase by up to 1 year**, as a technical specification takes on average 24 months from initiation to publication, and can be developed in 18 months[159]. This solution could be particularly useful in cases where no previous standards exist and there is a legislative deadline which would be difficult to meet by the normal standardisation process needed to develop standards[160]. The total yearly savings from conformity assessment costs for businesses is estimated at **EUR 23.5 million[161]**. Given its innovative nature for the ESS and the NLF, this measure may not be applicable to some sectors, which reduces its overall impact[162].

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[154] Only 18 % (45 out of 247) of respondents to the targeted survey to industry organisations and companies regard this measure as a potential cost.
[155] Targeted interviews with alternative SDOs and ESOs. However, concluding these agreements can be difficult, in particular to solve intellectual property rights issue, as shown by the example of the cooperation between ESOs and the open-source community in the development of hENs supporting the CRA.
[156] Throughout the IA and in line with Better Regulation practice, the total annual costs of 1 FTE in the Commission are estimated at EUR 194 000.
[157] The main pieces of Union legislation not already including the possibility to adopt CS and not covered by Omnibus IV are the General Safety Product Regulation (2023/988/EU), the Explosive for Civil Use Directive (2014/28/EU) and the Pyrotechnic Articles Directive (2013/29/EU).
[158] All 24 are requested to support the Pyrotechnic Articles Directive under Standardisation Request M/583.
[159] Based on CEN-CENELEC estimates in their Call for Evidence position paper and targeted interviews.
[160] This is the situation described in the case study 2 on AI (see Annex 15).
[161] This figure is obtained by multiplying the expected time reduction multiplied by the reduction in conformity assessment cost and the number of conformity assessments and companies in scope. The methodology is set out in Annex 4.
[162] This measure would for instance not be relevant for products with very long lifecycle, such as in the construction sector (see case study 1 in Annex 15). The measure is assumed to apply to 10 % of new requests. The EUR 23.5 million estimates take into account the fact that the measure would only apply to 10 % of new requests.

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Stakeholders generally support this policy measure and consider it effective: most respondents to the targeted survey, including a majority of SMEs, indicated that the use of technical specifications developed by ESOs as a basis for temporary presumption of conformity could help accelerate the development of high-quality standards[163]. CEN/CENELEC's European Agile Specifications (EAS) pilot projects are specifically designed for this purpose[164], providing a harmonisation effect within the internal market t and effectively preparing the adoption and diffusion of hENs[165]. Annex III organisations also support this measure as it allows ESOs to remain central actors of the ESS[166]. The measure can however decrease the inclusiveness of the standardisation process, as the standardisation deliverables providing temporary presumption of conformity do not benefit from the same level of consensus as a hEN.

The policy measure could incur additional costs to the industry if there are important changes between the deliverable providing temporary presumption of conformity and the final hEN. This could trigger additional adjustment costs for businesses to comply with the final hEN. Businesses however see this risk as limited[167]. No additional Commission resources would be required, as compliance assessments are already conducted on a continuous basis during development.

Measure 1.4: Improved strategic planning and accountability of the ESS

Better strategic planning and foresight of EU standardisation needs can have a **direct effect on the timeliness of the standardisation process**. This would notably facilitate the ESOs' preparatory work, in particular the identification and mobilisation of relevant industry experts as well as the inclusion of the potentially relevant alternative SDOs in their standardisation framework. Better strategic planning can **reduce the time required for the Commission to adopt standardisation requests**, particularly by shortening the consultation phase on draft requests. By better anticipating strategic standardisation needs, the Commission would be able to start the consultation process earlier and thus to cut the overall delivery time. While it is difficult to quantify this effect consistently, it is estimated that better strategic planning could lead on average to a **decrease of 3 months** in the Policy phase[168].

However, improved strategic planning can yield measurable effects only if the accountability of the standardisation process is ensured, and if there is increased trust that each step would be finalised according to the planning. The measure thus also foresees a more active monitoring of the standardisation process of ESOs by the Commission, notably through the implementation of deadlines for ESOs and the Commission at each step of the process. Increased transparency and accountability on performance can also lead to improvements in the publication phase,

[163] In the targeted survey to industry organisations and companies, 75 % of respondents (186 out of 247) indicated that technical specifications developed by ESOs would be a helpful measure where ESOs are unable to deliver hENs in a timely manner.
[164] Contributions from Call for Evidence and OPC; Targeted interviews to ESOs.
[165] The EAS would not have to be systematically implemented at national level by NSBs but NSBs would ensure that EAS do not conflict with existing ENs. This ensures the coherence of the standards' catalogue across the EU and the harmonisation effect across the internal market of the temporary presumption of conformity associated to the EAS. Targeted interviews with CEN/CENELEC.
[166] Targeted interviews with Annex III organisations.
[167] In the targeted survey to industry organisations and companies, 55 % (136 out of 247) of respondents considered a temporary presumption of conformity for technical specifications developed by ESOs to be a benefit for their organisation compared with only 20 % (49 out of 247) who considered it a cost.
[168] Stakeholders in targeted interviews have notably pointed out to the following sectors where lack of anticipation led to delays or no response by the ESOs: hydrogen infrastructure, low-carbon cement, cybersecurity, digital product passport, cybersecurity, quantum technology, and data exchange.

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where the lack of coordination between Commission, HAS consultants and ESOs leads to delays in the hENs' assessments. The potential improvement is estimated at 2 months[169]. The total duration of the policy and publication phases could be cut by 5 months in total, generating savings for the industry estimated at **EUR 109 million[170]** thanks to earlier availability of all hENs.

Stakeholders confirm the **positive effect of improved strategic planning on the responsiveness of the ESS**, identifying the HLF and the AUWP as the tools to implement better planning[171]. However, views are mixed as regards increasing the accountability of the ESS through stronger ESO obligations, monitoring and KPIs. The targeted survey to industry organisations and companies shows that 62 % (154 out of 247) of respondents consider increased accountability to contribute at most to a moderate extent to responsiveness[172]. Industry fears binding deadlines and KPIs could undermine consensus-building[173], while Annex III organisations and societal stakeholders strongly support them[174].

Improving strategic planning and increasing accountability of the ESS would incur limited additional costs to actors of the ESS. Only 9 % (23 out of 247) of industry respondents identified greater HLF engagement as a burden[175]. Ongoing digitalisation through the eNorm system will absorb increased ESO reporting requirements without raising administrative costs[176]. The Commission will have to mobilise 1 additional FTE to improve strategic planning and to monitor the performance of the ESS on a more systematic basis (based on current resources mobilised for the AUWP and the HLF).

Measure 1.5: Simplification and digitalisation

The proposed simplification measures have a direct effect on the responsiveness of the ESS by **cutting the time required by the Commission for the phases of the standardisation process it is responsible**. For the policy phase, the estimated gains in the adoption of standardisation requests are estimated at 3 months, mostly stemming from the Comitology procedure[177]. For the publication phase, the estimated gains of simplifying the referencing procedure coupled with better coordination of the assessment by HAS consultants could lead to an additional 2-month gain[178]. hENs would thus be available on average **5 months earlier than the baseline**, leading to savings for businesses of **EUR 109 million**, as this would apply to all hENs.

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[169] Impact assessment study, p. 44. Based on interviews with ESOs.
[170] This figure is obtained by multiplying the expected time reduction multiplied by the reduction in conformity assessment cost and the number of conformity assessments and companies in scope. The methodology is set out in Annex 4.
[171] In the targeted survey with industry organisations and companies, 64 % (158 out of 247) of respondents considered improved strategic planning aimed at addressing standardisation needs earlier in the technological life cycle to be a benefit.
[172] Targeted survey with industry organisations and companies.
[173] Contributions to the Call for Evidence and OPC; Targeted interviews with ESOs.
[174] Targeted interviews with Annex III organisations.
[175] Targeted survey with industry organisations and companies.
[176] The Evaluation estimated the total annual administrative costs linked to the Regulation at EUR 0.5 million combined for the 3 ESOs. The impact of the measure on such costs is estimated to be neutral compared to this baseline, given that the increased monitoring efforts would be compensated by the facilitated reporting through better integration of IT systems.
[177] Impact assessment study, p. 44. See also Annex 9. The estimated time for the Comitology procedure is between 2 and 6 months, with a minimum time for voting of 2 months.
[178] Impact assessment study, p. 44.

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The measure will further contribute to the responsiveness of the ESS by ensuring that the gains from digitalisation by ESOs described in the baseline are materialised through the legal requirement to offer standards in a machine-readable format. A **strong consensus** over this measure was registered in the survey sent to industry organisations and companies[179]. This would also allow to speed up the assessment phase as HAS consultants would have easier access to the offered standards. The simplification exercise would be coupled with the introduction of internal but transparent deadlines at each step of the Commission's processes, with monitoring activities conducted under measure 1.4. This would **foster actual compliance with the new shorter process**. In addition, in the OPC, 85 % of businesses agreed that the Commission's procedures for the request, evaluation and citation of hENs should be simplified[180].

This measure, while contributing overall to the responsiveness of the ESS, may also in some cases lead to **increased uncertainty**. The comitology procedure, while in a very large majority of cases mostly formal, contributes to the alignment of interests between the Commission, Member States, ESOs and Annex III organisations. While removing comitology could increase Member State disagreements and use of the formal objection mechanism, this risk is mitigated by the simultaneous simplification of that procedure.

The simplification measure will not induce any additional costs to the actors of the ESS; it would bring limited administrative costs reduction for the Commission by reducing the administrative process linked to the comitology procedure, partially offset by increased resources to manage formal objections and estimated as a reduction of 0.5 FTEs.

6.2.2. Policy Option 2: ESS centred on ESOs with new flexibilities

Measure 2.1: Flexibility to address standardisation requests to alternative SDOs

The flexibility for the Commission to directly address a standardisation request to an alternative SDO could lead to **a significant decrease in the time to deliver hENs.** This could be achieved either through their faster delivery in their field of expertise, or by directly requesting them existing standards or technical specifications that would already cover essential requirements.

As outlined in section 2.1.1, many alternative SDOs claim a faster standard delivery time than the current average by ESOs, with an average duration process between 6 and 18 months[181]. **The estimated time for obtaining a hEN from a SDO is thus estimated at 12 months**, considering that the Commission will only use this possibility when the expectations of fast delivery would be high, based on consultation with ESOs and alternative SDOs. This faster delivery time would however be limited by the need to pre-consult ESOs prior to addressing the request to an alternative SDO as well as by the validation by Member States of the standardisation request through the Comitology procedure, adding an estimated 3 months to the

[179] 77 % (190 out of 247) of respondents to the targeted survey to industry organisations and companies supported a fully digitalised standard development process, including an integrated OSD platform and machine-readable formats. Case study 1 on construction products highlights the strong support for digitalisation of standards to improve efficiency, traceability and accessibility, while also facilitating their integration in emerging new tools such as DPP and reduce administrative burdens on SMEs. See Annex 15.
[180] Contributions from OPC, sorted by companies and industry associations, (225 respondents out of 301).
[181] One sector-specific SDO reported in the OPC to be able to provide a standard in 6 months.

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policy phase[182]. Overall, this could bring the total standard delivery time in such cases to **3.3 years**.

The measure is expected to **generate annual savings for businesses** estimated at **EUR 52 million overall[183]**. Its impact depends largely on the extent to which it will be used and on the number of requests that will be addressed to alternative SDOs. While it is difficult to forecast precisely the extent to which the Commission will implement the new flexibility, it will remain a supporting option, targeted at sectors where alternative SDOs can be more efficient than ESOs, in particular in the digital sector and the transport sector. Based on the upcoming planning of standardisation requests in the AUWP, it is estimated that no more than 10 % of standardisation requests would be addressed to alternative SDOs – for an average of 1 or 2 requests per year. The estimation of savings for the industry is of course sensitive to this assumption, as well as to the ability of alternative SDOs to effectively deliver hENs within the shorter timeframe.

Stakeholders expressed uncertainty regarding the possibility of opening the ESS to other SDOs. In the OPC, 61 % of businesses' respondents (182 out of 297) disagreed that the Commission should have the option to request the development of new standards to alternative SDOs even under the conditions that they work in an inclusive manner with balanced participation of relevant European stakeholders[184]. The remaining 39 % (115 out of 297) either agreed or were neutral, suggesting divergent views across sectors and company sizes, in line with the design of the measure targeted at specific cases. The case study on critical space technology showed for example that this sector would support standardisation requests to be addressed to alternative SDOs, in the absence of a competent ESO for upstream space technologies[185]. Furthermore, industry's resistance often stems from implementation concerns (*e.g.*, ensuring coherence with existing frameworks, avoiding fragmentation, or maintaining the ESS's global credibility) rather than outright rejection of flexibility[186]. NSBs are likewise divided on the possibility of requesting, using and referencing standards from alternative SDOs, with 57 % (21 out of 37 respondents) expressing opposition to this measure.

The possibility of addressing standardisation requests to alternative SDOs, coupled with the right of ESOs to assess requests in priority, will also **increase competition across SDOs and put more pressure on ESOs to improve their process** to continue delivering hENs to the Commission. This will also create dynamic benefits as ESOs would have additional incentives to deliver hENs on time for the requests they have accepted to prevent the Commission to address future requests to SDOs. The pre-consultation mechanism between the Commission and ESOs will also help identify the best-placed SDO for each request, based on sectoral expertise, reducing the number of cases where hENs are delivered late or not at all.

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[182] As a significant departure from current practice of the ESS, addressing a standardisation request to an alternative SDO would require consultation and validation from the Member States, in particular since the different national interests would not be formally represented in the standardisation process managed by an alternative SDO contrary to the process managed by ESOs where NSBs are instrumental in aggregating national participation through the national delegation principle.

[183] See Annex 4 for methodology.

[184] Results of the OPC, sorted by companies and industry associations.

[185] See case study 4 in Annex 15.

[186] For example, the EU has already adopted alternative models in certain areas (*e.g.*, the Corporate Sustainability Reporting Directive's EFRAG standards or the European Health Data Space's CS, see Annex 13), showing that exceptions are possible when aligned with strategic priorities.

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The measure will incur adjustment costs for stakeholders of the ESS, as companies concerned may need to duplicate their investments in standardisation to participate both in ESOs and alternative SDOs – in particular if they concern overlapping technologies. While the OPC showed that companies view this more as a cost than a benefit (37 % of respondents expected high or very high costs, 41 % low or very low benefits[187]), this measure is expected to be applied in a small number of cases[188] and in specific sectors. These costs could be a relatively higher barrier to participation for SMEs and Annex III organisations, whose ability to engage in multiple SDOs is lower. A rough and upper-bound estimate of such additional costs for businesses would be **EUR 4.5 million** per year[189] and for Annex III organisations **EUR 0.1 million per year**[190].

The measure will also incur **additional administrative costs for the Commission** to organise and manage the use of the flexibility to address standardisation requests to alternative SDOs. The Commission will first have to mobilise additional resources to identify relevant alternative SDOs and assess if they comply with the quality criteria necessary to deliver hENs. In addition, it will have to monitor the activities of alternative SDOs to assess on which sectors and technologies they could bring value added in the delivery of hENs, in a more proactive manner than for measure 1.2. Last, the management of the standardisation requests to alternative SDOs will likely require more oversight from the Commission, at least for the first requests addressed to each new alternative SDO. As these are largely new tasks for the Commission, there is no benchmark to accurately assess the resources needed, but a conservative estimate would be 3 FTEs, based on the experience of the CRA standards, which involve other standardisation fora together with the ESOs.

Measure 2.2: EU Expert Centre led by a CSO

The creation of an EU Expert Centre led by a CSO aims to support the implementation of Policy Option 2. It would host **the new tasks of the Commission**, in particular relating to requests to alternative SDOs, as well as formalise the **coordination of the internal network of standardisation experts** across Commission services. It will improve the Commission's oversight and coordination in standardisation, increasing the accountability of the ESS and its international influence. 58 % of respondents to the targeted survey to industry (144 out of 247) organisations and companies support its creation due to its potential to improve coordination and EU influence in standardisation[191]. ESOs and NSBs also support the measure[192]. The Expert Centre would gather **a total of 20 FTEs**[193] with a central supporting role and coordinate the network of over 60 staff regularly involved in standardisation within the Commission, which would have to conduct new additional tasks at sectoral level. This organisation would allow to

[187] Results of OPC, sorted by companies and industry associations.
[188] This impact assessment assumes 10 % of request will be submitted to alternative SDOs.
[189] A DG GROW 2021 study estimates the total costs of developing a EN at EUR 0.8-1.0 million. Considering an average duration for hEN of 3 years, the duplication of the full participation costs for all standards requested to alternative SDOs would lead to EUR 4-5 million additional costs compared to the baseline (assuming 10 % of new hENs requested to alternative SDOs). Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, November 2021, pp. 72-73.
[190] The Evaluation estimated the annual average costs of participating in technical discussions for all Annex III organisations at EUR 1.3 million (Evaluation of the Standardisation Regulation, p. 45). Duplicating participation in alternative SDOs for 10 % of hENs would lead to an increase of EUR 0.1 million, which would in practice require increased financing by the Commission. This effect is considered negligeable.
[191] Targeted survey to companies and industry associations.
[192] Workshop with NSBs.
[193] The 16.5 FTEs of the current standards policy unit, plus the 4 additional FTE required for the new tasks identified at central level, minus 0.5 FTE linked to implementation of Measure 1.4.

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increase synergies across the Commission's standardisation activities and to enable the new needs to be covered through redeployment of existing resources. The new tasks and additional resources' needs of the Expert Centre would include[194]:

- Supporting the integration of specifications from other SDOs by ESOs (Measure 1.1): 1 FTE, decentralised in the sectoral services.
- Implementing the strategic planning and the increased accountability of the ESS (Measure 1.4): 1 FTEs, centralised in the Centre.
- Supporting the implementation of the flexibility to address requests to alternative SDOs (Measure 2.1): 3 FTEs, out of which 1 centralised in the Centre.
- Improving international coordination across EU standardisation actors (Measure 1.9 and Measure 2.5): 2 FTEs, out of which 1 centralised in the Centre.
- Leading the Centre (CSO, Measure 2.2): 1 FTE.

6.2.3. Policy Option 3: Open ESS managed by the Commission

Measure 3.1: Open selection of SDOs for standardisation requests

This measure enables the Commission to address standardisation requests to any SDO, leading to an increased number of hENs requested to SDOs compared to Measure 2.1. **Its effectiveness relies on the assumption that alternative SDOs would be on average more efficient than the current ESOs**, either because they have better expertise in a given field or because existing ESOs face resource constraints. This would introduce higher competition for the delivery of hENs to the Commission and can indirectly contribute to improve the responsiveness of all actors, alternative SDOs and ESOs. However, this approach can carry risks to both quality, as the trust and legitimacy of the ESS could be undermined by a decreased reliance on ESOs, and inclusiveness, as the representation of societal interests could be lower in alternative SDOs. The annual savings for businesses compared to the baseline is estimated at **EUR 171 million**[195].

ESOs and NSBs would incur no additional costs but are opposed to this measure, as they expect it would fragment the ESS, duplicate resources, and undermine the consensus-based approach guaranteed by the current system[196]. Stakeholders' views are also overall negative, 55 % of companies and business associations disagreed with opening the standardisation framework to other organisations while 32 % agreed[197]. The measure will likely lead to **duplication of industries' participation costs** (adjustment costs)[198], more than the targeted flexibility of measure 2.1 since it would cover a wider range of hENs. Estimating these additional participation costs is challenging as this would largely depend on the degree of

[194] The additional costs from these tasks have been allocated to each corresponding policy measure. The only additional resource from this measure specifically is the position of the CSO.
[195] The measure could reduce the time for the delivery phase to 1.8 years on average, assuming that ESOs would deliver hENs according to the average duration of Policy Option 1 and SDOs according to the average duration of Measure 2.1. Given their wide sectoral expertise and well-established position as lead standardisation bodies in the EU, it is estimated that ESOs will continue delivering 67 % of requests.
[196] In the OPC, 78 % of NSBs (28 out of 36 respondents) strongly disagreed with introducing open selection of SDOs for standardisation requests. The workshop with NSBs confirmed their strong opposition to the measure.
[197] Results of OPC, sorted by companies and industry associations. 161 respondents out of 291 disagreed, 92 agreed.
[198] Targeted survey with companies and industry associations. Respondents were uncertain about the impact of this measure on their organisations, with 37 % (92 out of 247) considering open procurement of standards without preferential treatment for ESOs to represent a cost, while 32 % (79 out of 247) regarded it as a benefit.

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sectoral overlaps across SDOs delivering hENs to the Commission. A rough estimate of such annual additional costs for businesses would be **EUR 15 million**[199].

The Commission would also bear **additional administrative costs** due to the need to monitor a **more complex standardisation system**. The Commission would have to mobilise resources beyond those introduced to support Measure 2.1 as it would have to manage more requests addressed to more SDOs. Based on current resources mobilised to manage the ESS, the Commission would need 6 additional FTEs compared to the baseline[200].

Table 1: Overview of savings for businesses for Specific Objective 1 by Policy option[201]

Total duration of each phase in years and savings for businesses compared to the Baseline	Phase A: Policy phase	Phase B: Delivery phase	Phase C: Publication phase	Total average duration	Share of use of hEN path	Financial savings (EUR million)
Current situation	**1.7**	**3.2**	**1.2**	**6.1**		
Baseline	**1.7**	**2.4**	**1.2**	**5.3**		
Policy option 1*	**1.2**	**2.2**	**0.9**	**4.3**		**265**
Standards obtained from ESOs through measures 1.1	1.2	1.5	0.9	3.6	10%	45
Standards obtained from ESOs through measure 1.3	1.2	1.5	0.9	3.6	10%	45
Other standards obtained from ESOs	1.2	2.4	0.9	4.5	80%	174
Policy option 2*	**1.2**	**2.1**	**0.9**	**4.2**		**295**
Standards obtained from ESOs through measure 1.1	**1.2**	**1.5**	**0.9**	**3.6**	**10%**	45
Standards obtained from ESOs through measure 1.3	**1.2**	**1.5**	**0.9**	**3.6**	**10%**	45
Other standards obtained from ESOs	**1.2**	**2.4**	**0.9**	**4.5**	**70%**	152
Standards obtained from alternate SDOs through measure	**1.5**	**1.0**	**0.9**	**3.3**	**10%**	52
Policy option 3	**1.3**	**1.8**	**0.9**	**4.0**		**348**
Standards obtained through ESOs (based on PO1)	**1.2**	**2.2**	**0.9**	**4.3**	**67%**	**177**
Standards obtained through other SDOs (based on 2.1)	**1.5**	**1.0**	**0.9**	**3.3**	**33%**	**171**

Measure 3.2: EU Standardisation Office

The creation of **an EU Standardisation Office is necessary for Measure 3.1 to function effectively** as the Commission will have to organise the selection of SDOs for each standardisation request and manage the financing of EU standardisation needs. The Office would regroup all existing and additional resources in the Commission involved in the implementation of the Standardisation Regulation for a total of 61.5 FTEs: the existing standards policy unit (16.5 FTEs), an additional estimated 15 FTEs required for carrying the new tasks under policy option 3, as well as the current resources in sectoral services of the

[199] The same methodology as for Measure 2.1 is used, with a larger extent of possible duplication.
[200] The resources needs are based on one third of the current team in charge of managing the ESS to mirror the share of request from hENs, thus 6 FTEs.
[201] The table presents the savings for each path used to request hEN in each Option, resulting from the relevant combination of policy measures assessed in Section 6.2. For instance, standards obtained in Policy Option 1 from ESOs through measure 1.1 benefit from the effects of measure 1.1 and from the effects of measure 1.4 (strategic planning) and 1.5 (simplification) that apply to all hENs. Details of the breakdown by policy measure is provided in Table 4.2 in Annex 4. Totals may differ due to rounding.

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Commission implementing the Standardisation Regulation (30 FTEs, see Annex 12). The new tasks and additional resources' needs of the EU Office[202] would include:

- The relevant tasks and resources of the Expert Centre, including the CSO: 8 FTEs[203];
- The additional resources needed to manage the requests addressed to SDOs other than the ESOs, including the additional support to Annex III organisations to be involved in SDOs' standardisation process (measure 3.1 and 3.4): 4 FTEs.
- The management of the budget and the negotiations of agreements to ensure publication of hENs in the OJEU (measure 3.3): 2 FTEs.
- The support to the international dimension of the open system (measure 3.5): 1 FTE.

Such an Office centralising the Commission's resources active in standardisation could generate efficiency gains and a better implementation of the Regulation, through experience and expertise building. However, it would bear the important risk of losing the sectoral expertise necessary to steer the standardisation process and to assess whether hENs satisfy the requirements they aim to cover. The possibility to have the tasks of an EU Standardisation Office aggregated into a joint office or Authority for NLF and Market Surveillance (the other elements of the upcoming EPA) was considered, but no potential synergies or overlaps were identified which would justify such a joint Office. The tasks considered under measure 3.2 do not have any direct relevance for market surveillance nor for the implementation of the NLF provisions.

6.3. Impacts on Specific Objective 2: Ensuring a financially viable and inclusive ESS

The assessment under this objective combines monetised and non-monetised impacts. Quantification is feasible for some effects, notably certain costs for NSBs and transfers linked to access to hENs, but more limited for other elements such as the quality of participation or the practical influence of societal stakeholders. The analysis therefore combines cost estimates with qualitative evidence from interviews, surveys, case studies and validation workshops.

6.3.1. Policy Option 1: Modernised ESO monopoly

Measure 1.6: Strengthened obligations on NSBs to include civil society organisations

As mentioned in section 2.2.2, civil society organisations face a specific challenge to participate in standardisation at national level. If implemented by NSBs, **the measure can have a moderate positive effect on the inclusiveness at EU level** by addressing one of the key "gaps" in ESS inclusiveness. Annex III organisations and societal stakeholders consulted expressed strong support for this measure, as it would help increase inclusiveness by levelling the differences currently present at national level[204]. However, the measure remains voluntary for NSBs, and its impact depends on the number of NSBs implementing the best practices identified in Article 6 of the Standardisation Regulation and the extent of their implementation. Its impact should not be overestimated as Annex III organisations have limited representation at national level and they face resources constraints, such as staff availability, beyond the headline cost of participation[205]. **While increasing inclusiveness may lengthen time for**

[202] The additional costs from these tasks have been allocated to each corresponding policy measure. There are no additional costs relating to setting up of the Office itself.
[203] All tasks identified for the Expert Centre, excluding savings from Measure 1.4 not applying in Option 3.
[204] Impact assessment study, p. 52.
[205] For instance, ECOS is the only EU organisation representing environmental interest in standardisation.

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consensus building, this risk remains limited as the measure fosters broader early-stage participation and will be further facilitated by the digitalisation of the standardisation process[206].

The measure will create **adjustment costs for the NSBs** which will be borne principally by those that do not have such mechanisms in place. These costs are driven by a large set of different measures across NSBs to extend Article 6 best practices to civil society organisations and reflect both direct resource allocation and foregone revenue associated with facilitating participation. These costs are estimated at EUR 1.2 million per year[207].

Measure 1.7: Increased incentives to foster experts' participation in standardisation

This measure is expected to be effective in improving the sustainability of the ESS by **increasing the participation of experts** in the standardisation process, in particular from the R&I community. Addressing the targeted barriers to R&I experts' participation could significantly increase the quality of hENs as expertise is the key driver of a successful standardisation process[208] and could contribute to the renewal of standardisation experts, further strengthening the sustainability of the ESS. The case study on additive manufacturing indicated that facilitating participation of experts from the R&I community could help reducing the gap in these technological sectors[209].

The results of the targeted survey with industry organisations and companies, including SMEs, confirm the effectiveness of such measures. 70 % (173 out of 247) of respondents agree that promoting a standardisation ecosystem better connected to innovation and pre-normative work would be beneficial[210]. The results of the OPC also outlined a wide level of agreement among Annex III organisations and societal stakeholders on fostering capacity building of European experts[211]. Stakeholders also highlighted that the main effect on participation of experts would be achieved through increased public financial support[212].

Measure 1.7 is not expected to generate significant direct costs for stakeholders. The main project conducted so far in the framework of the HLF workstream on Education and Skills (the pan-European standardisation certificate[213]) has been collectively developed for free through the mobilisation of the standardisation community. Some adjustment costs could incur to the ESOs and NSBs to provide access to draft standards to researchers for free[214]. The improved

[206] Targeted interviews with Annex III organisations.
[207] Impact assessment study, p. 52-53. The average costs per NSB to extend the inclusiveness best practices for SMEs to civil society organisations are estimated based on the costs of the current measure in place for SMEs. The estimates have been derived from data provided by 14 NSBs through targeted interviews and surveys. The total additional adjustment costs are estimated considering that only the NSBs that do not already provide such types of measures would implement them.
[208] Targeted interviews with ESOs and the industry.
[209] See Annex 15.5.
[210] Targeted survey to industry organisations and companies.
[211] Results of the OPC. 71 % of civil society respondents strongly agree (27 out 38) and 26 % somewhat agree (6 out of 38).
[212] Financial support or free access measures to facilitate SME participation in TC received notable support in the OPC. In the dedicated SME Workshop, participants identified these measures as one of the key factors to encourage SMEs participation, notably in international standardisation.
[213] Recommendation on the pan-European Certificate of Knowledge in Standardisation, HLF.
[214] Free access to draft standards has been estimated at EUR 25 000 per NSBs for SMEs in Measure 1.6; granting similar access to researchers would likely bring only marginal additional costs.

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coordination of existing scattered EU public financial support to experts' participation in standardisation would also not increase the costs for the Union but could lead to efficiencies[215].

Measure 1.8: Transparency requirements for participation in standardisation

Introducing transparency requirements to participate in standardisation would provide **greater legitimacy** to hENs that are part of EU law and would ensure that their development complies with the principles of transparency, openness and good governance. Transparency regarding the interests represented and active in the standardisation process can also contribute to foster participation from under-represented interests, notably civil society and SMEs, and could lead to increase the overall quality of the process. While transparency requirements may also have a chilling effect on the participation of some actors, it is overall considered a measure with a positive effect for the sustainability of the ESS, as outlined by the results of the OPC[216]. Annex III organisations and societal stakeholders highlight the need to enhance transparency regarding the stakeholders involved in TCs developing hEN[217] and for ESOs to strengthen their monitoring and recording activities of the composition of TCs working on hENs.

This **measure is expected to generate administrative costs for ESOs** as they would have to set up public platforms disclosing entities and interests working on hENs. As the information is largely already available to ESOs, the main costs are the platform set-up (estimated at EUR 0.5 million one-off) and maintenance (estimated at EUR 0.6 million per year) to systematically track participation of the 90 000 experts active in standardisation[218].

6.3.2. Policy Option 2: An ESS centred on ESOs with new flexibilities

Measure 2.3: Free and unrestricted access to hENs from central repository

This measure would improve the conditions of access to hENs and reinforce the legal sustainability of the ESS. Free and unrestricted access through a repository accessible without prior authentication would significantly contribute to improve access to hENs and compliance with the judgments of the CJEU. In the OPC, most industry actors and societal stakeholders agreed that hENs should be freely accessible, while ESOs and NSBs held the opposite view[219]. The measure can also have **positive spill-over effects** as it would foster the use of hENs by all stakeholders – industry, SMEs as well as civil society representatives and the general public and decrease compliance costs of businesses as they would no longer have to pay for hENs, saving EUR 30 million per year.

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[215] Since the revision of the Standardisation Regulation will enter into force during the next MFF, there is no information on the future available EU budget for standardisation. It is assumed to be constant. However, the new MFF organisation, and notably the future European Competitiveness Fund (ECF), is an opportunity to better coordinate EU investments in standardisation, in line with the objectives of the ECF.

[216] In the OPC, 57 % of NSBs (20 out of 35 respondents) indicated they strongly agree with the measure.

[217] OPC results, 74 % of Annex III organisations and societal stakeholder strongly agreed.

[218] Impact assessment study, p. 57. One-off costs to set up such platforms are usually low. The maintenance of the platform will require resources to monitor that the information is up-to-date, complete and accurate.

[219] OPC results, 71 % of industry respondents (204 out of 291) and 74 % of Annex III and societal stakeholders respondents (29 out of 39) agreed that the legally relevant content of standards should be published and freely accessible. ESOs and NSBs disagree with the statement at 83 % (29 respondents out of 35).

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However, this measure may **challenge the financial sustainability of some NSBs**, and in turn, the current functioning of CEN/CENELEC[220]. NSBs' business models rely to various degrees on the sale of hENs to finance their activities – see section 2.2.3 and Annex 8. The measure could thus endanger the financial viability of certain NSBs, putting the national delegation principle on which CEN/CENELEC model is based at risk. It could also endanger CEN-CENELEC and NSBs' capacities to finance their part of the standardisation development process, if they cannot recoup their investments in delivering hENs. The free and unrestricted access to hENs implies a shift of the financial burden of the standardisation development process currently borne by the users of hENs (through their purchase of hENs) to the ESOs and NSBs (through a loss of revenues). This additional financial burden on ESOs and NSBs could decrease their ability to develop hENs and to accept standardisation requests from the Commission. The contributions from industry to the Call for Evidence and the OPC point out to the need to compensate the foregone revenues for CEN/CENELEC and its NSBs due to the free and unrestricted access to hENs to ensure the economic sustainability of the ESS. At the same time, as the cost to develop hENs is mostly borne by the industry and is broadly disconnected from the revenues generated by the sales of those hENs by NSBs, the measure is unlikely to affect the industry's incentives to participate in standardisation[221].

The measure will result for CEN/CENELEC and its NSBs in a maximum revenue loss of EUR 30 million per year, amounting to the total annual sales of hENs. However, the actual impact on revenues could be lower due to several factors linked to the requirements on access:

- **Conditions of access**: downloadable versions of hENs would likely lead to a higher impact on revenues losses for NSBs.
- **Business practices linked to purchasing standards**: many users have a subscription to the platforms of NSBs providing access to the entire standards portfolio, which is not limited to hENs (which only represent a small share – 12 % – of this portfolio).
- **Object of access**: access could be granted to the full hENs or only to its legally relevant part[222]. In the latter case, most businesses consider that this would not be sufficient for their work[223]. Hence it is likely that many users will continue purchasing the full hENs if only the legally relevant part is accessible free of charge.

There is insufficient information on the marketing activities of CEN/CENELEC and NSBs to precisely assess how such factors would impact the actual revenue loss. Moreover, the impact could be **further mitigated as they are moving from a document-centric model towards a data-centric model** for standards and hENs – see section 5.1. The digital transformation of ESOs and NSBs could enable them to compensate the foregone revenues of hENs by new value-added services to the industry through SMART standards, based on the copyrights they claim

[220] The financial sustainability of ETSI would not be affected by the measure, as ETSI standards already benefit from free and unrestricted access, the costs of the standardisation process for hENs being mostly borne by the participants to the standardisation process through membership fees.
[221] Industries are not financially compensated for their participation in standardisation activities. Instead, they benefit from having a voice in shaping market trends and from the efficiency linked to adopted standards.
[222] Extracting the legally relevant parts from the existing hENs (based on the Annex Z) or developing legally relevant parts distinctively from the rest of the standard in new hENs could be challenging in practice. CEN/CENELEC could choose to grant free access to the full hENs rather than only the legally relevant parts independently from legal requirements.
[223] Results of the OPC. Access to the legally relevant part would be insufficient for 66 % of industry respondents (190 out of 289).

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on hENs, ensuring that ESOs and NSBs retain a financial interest in developing hENs at the request of the Commission. Many NSBs are already selling, and expanding, such services[224].

The measure will impact mostly the NSBs that are more reliant on the sales of hENs and are less ready to move to a data-centric model, either due to lack of resources or lack of a perceived market for such services in their Member States[225]. Targeted support could be necessary to ensure the financial sustainability of all NSBs and of the ESS. The annual cost to support the NSBs most financially exposed to the free access to standards could be around EUR 6 million, assuming that access to the full hENs is granted[226]. This compensation could be granted by the Commission through an increase in operating grants to ESOs, that would then distribute it across relevant NSBs[227]. This increased compensation could be absorbed by the current EU budget earmarked for standardisation. However, this would decrease by the same amount the action grants of the Commission to finance experts' participation (mostly benefiting businesses) to standardisation.

The measure entails limited direct operational costs for ESOs to set up the repository. NSBs have indicated a willingness to manage such a repository and to host the hENs to which access is granted, which would allow them to maintain their relationship with their customers. The investments already incurred to set up the readability platforms are likely to cover the costs of the central repository as only limited changes would be necessary. CEN/CENELEC are also considering hosting hENs from other SDOs on their repository to be able to provide a comprehensive service of access to hENs. However, the repository would fulfil a legal requirement and a public service that the Commission will have to enforce. This could be achieved through a repository managed directly by the Commission, based on the current eNorm database, that would ensure centralised access to the catalogue of hENs and the integration of hENs from alternative SDOs, redirecting users to the ESOs' repository. Limited additional costs are expected in view of the investments already incurred to develop the readability platform of the Commission[228].

Measure 2.4: Binding requirements on NSBs on including SMEs and civil society

The effects of this measure will be similar to the effects of measure 1.6 but with a **higher effectiveness given its legally binding nature**[229]. Evidence from the OPC suggests broad recognition of the potential of stronger legal obligations, although views differ regarding their likely effectiveness and the type of measures considered most impactful[230]. Most respondents

[224] Targeted interviews with NSBs.
[225] Workshop with NSBs.
[226] NSBs financial exposure to the sales of hENs varies widely, from 1 % to 25 % of their total revenues. Assuming a compensation up to 5 % of revenue loss, the support would concern 14 NSBs for a total of EUR 6 million. If the support is targeted on smaller NSBs, generating less than EUR 20 million per year, regardless of their exposure to hENs, the support would amount to EUR 5.5 million and benefit 20 NSBs.
[227] The loss in hENs' sales could also be compensated by increased public financing from Member States or by an increase in NSBs' membership fees, moving closer to the standardisation model of ETSI and other SDOs. For the IA, the assumption is that the EU budget would cover the compensation.
[228] The measure will not have impact on resources in the Commission as the new tasks created to oversee the implementation of central repository could be covered by the redeployment of staff implementing the readability platforms and managing access to document requests to standards.
[229] In case study 1 on construction products, the results of a targeted survey suggest that binding legal requirements on NSBs for involving SMEs could be effective in the construction industry (see Annex 15).
[230] Contributions to the Call for evidence and position papers from the OPC.

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to the targeted survey to industry organisations and companies (61 %, 151 out of 247) also consider that strengthening legal obligations would improve inclusiveness[231].

This measure is expected to generate adjustment costs for the NSBs. Applying the same methodology as for measure 1.6, these costs are estimated to reach EUR 1.9 million, as it would require several NSBs to increase their support to both civil society and SMEs[232].

6.3.3. Policy Option 3: Open ESS managed by the Commission

Measure 3.3: Publication of hENs in the OJEU

This measure ensures access to hENs by publishing their text in full in the OJEU, regardless of whether they are delivered by ESOs or alternative SDOs. The publication of hENs in the OJEU will solidify the legal status of hENs as part of EU law. It would benefit all users who would be able to consult, download and use them for free – businesses as well as stakeholders involved in standardisation, notably the R&I community.

However, the measure would strongly **challenge the financial sustainability of the standardisation process** supporting Union policy and legislation**.** The publication of hENs in the OJEU will have much broader effects on the ESOs and NSBs' revenues than measure 2.3. First, it will lead to a total loss of revenue from the sales of hENs for NSBs, for an amount of EUR 30 million. Second, it would hamper the ESOs' ability to offer value added services based on hENs and recoup the costs incurred to develop them. ESOs would still be able to offer such services but would lose their privileged position and face potential competition from other actors. According to some NSBs, this could lead to a decrease in the overall trust in standards, as such actors would not be able to offer the same guarantee of quality as ESOs[233]. ETSI would be affected as well as it claims copyrights on the standards it adopts. The publication in the OJEU would also affect the ability of the Commission to obtain standards from alternative SDOs as their incentives to engage in the standardisation process would be limited if they cannot claim copyrights on these hENs.

The measure might lead to a **loss of revenues from ESOs that goes beyond the sales of hEN** as it would also decrease the potential for selling services relying on hENs. There is no information on the share of current revenues from ESOs not directly linked to sales that depend on hENs, but an estimate would be EUR 18 million[234]. To ensure the sustainability of the ESS, the Commission may need to financially support ESOs and SDOs to deliver hENs; the actual costs incurred are difficult to estimate as there is no benchmark for such support, but the total budget needed would likely amount to at least EUR 15 million[235], exceeding the flexibilities of

[231] Targeted survey to industry organisations and companies.
[232] Impact assessment study, p. 58.
[233] Workshop with NSBs.
[234] Assuming that the total revenues from NSBs (EUR 500 million per year) are related to standardisation activities, and assuming that such revenues are proportional to the actual sales of standards, this would indicate an estimate of EUR 18 million in hEN-related services for the NSBs from CEN/CENELEC, which would be at risk in addition to the EUR 30 million of direct sales. Impact Assessment Study, p. 60.
[235] Building on the 2021 DG GROW study estimating the total costs of developing a standard at EUR 0.8 to 1 million, the maximum costs would be EUR 120-150 million for an average of 150 hENs adopted per year. However, the actual share of costs incurred by SDOs is lower; the industry usually considers that they cover 90 % of the total costs for developing a standard, which would bring the estimate down to EUR 12-15 million. These estimates are indicative and only concern new hENs. Applying the same reasoning to the stock of hENs would not be relevant as the value of an adopted hENs depends on its amortisation over time.

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the current EU budget for standardisation[236]. As a consequence, the Commission may need to reduce the number of hENs requested, thus having a negative impact on the functioning of the internal market. Finally, the publication in the OJEU would have an impact on the timeliness of their legal effect, as they would have to be translated in all other EU languages, which would also increase the costs of the measure[237]. This will also require new tasks for the Commission such as negotiating the conditions of publication in the OJEU and managing the corresponding budget, which are estimated at 2 FTEs.

Measure 3.4: Fostering inclusiveness in alternative SDOs

The measure will increase the inclusiveness and quality of the hENs offered by alternative SDOs. 61 % of SME respondents in the targeted survey considered the measure to have a positive effect on inclusiveness and participation[238]. Annex III organisations however expressed concerns that such obligations for alternative SDOs would remain formal and would not contribute to their effective influence. Mandatory inclusiveness requirements to each request to an alternative SDO were viewed as a necessary pre-condition by stakeholders[239]. However, the potential increase in the number of alternative SDOs developing hENs will likely challenge maintaining the current level of inclusiveness of the ESS. The adaptation of Annex III organisations, and more generally of SMEs and civil society experts, to the alternative SDOs may take time and risks fragmenting their effective participation.

This measure will generate additional costs for the Commission, that would have to support Annex III organisations' participation in standardisation in alternative SDOs to ensure a high level of inclusiveness across all hENs[240]. Ensuring inclusiveness in alternative SDOs would require one additional FTE in the Commission to monitor their actual practice and to support Annex III organisations in their participation work in multiple alternative SDOs.

6.4. Impacts on Specific Objective 3 – International influence

This objective is intrinsically more difficult to quantify than Specific Objectives 1 and 2. Its geopolitical and strategic dimensions, including the possible benefits of stronger reflection of EU values and interests and the possible costs of decoupling from the "international first" principle, do not lend themselves to robust monetisation on the basis of the available evidence. The assessment for this objective therefore relies predominantly on qualitative evidence, including stakeholder surveys, interviews, case studies.

6.4.1. Policy Option 1: Modernised ESO monopoly

Measure 1.9: Improved EU coordination

This measure will **strengthen the EU's impact in international standardisation** by supporting a more coherent and coordinated EU voice. The experience of the HLF highlights

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[236] In this option, all the available budget currently targeted at fostering experts' participation in standardisation under the SMP (EUR 10 million per year) would be absorbed the compensation, leaving a gap of EUR 2-5 million.
[237] There are limited benchmarks available to assess translation costs of hENs. The Commission financed several projects for translating hENs into Ukrainian in 2024. In this project, the average cost of translation of one hEN is EUR 1 000. This would lead to total costs of maximum EUR 69 million to translate the entire portfolio of hENs in all languages (3 270 standards in 21 languages, as hENs are generally available in French, German and English).
[238] Targeted survey to industry and companies, 91 out of 148 SME respondents.
[239] Interviews with Annex III organisations.
[240] The estimated additional costs are EUR 0.4 million using the same approach as for measure 2.1. Similarly to measure 3.1, this would decrease the action grants to support industry experts' participation.

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that better coordination across all European stakeholders involved in standardisation – industry, ESOs and NSBs, Member States and the Commission – can increase collective involvement in priority standardisation processes at international level[241]. 73 % of industry representatives consulted in the targeted survey indicated that increased Commission involvement and coordination of EU experts would strengthen EU impact in ISOs from a moderate to a very high extent[242]. Stronger EU coordination was considered particularly necessary to promote shared strategic positions in innovative sectors such as fuel cells, circular economy, cybersecurity, AI or quantum[243]. This view is also shared by Annex III organisations and national societal stakeholders[244], whereas ESOs and NSBs insist on the importance of ensuring their independence in ISOs.

Additional coordination efforts will incur administrative costs for the Commission. The additional costs for the Commission are estimated at 1 FTE to animate the network of EU stakeholders involved in international activities, based on the current experience of the HLF. In the targeted survey to industry organisations and companies, respondents do not identify increased coordination as additional costs[245].

Measure 1.10: Possibility to restrict participation in standardisation to EU/EEA

This measure can be **effective to provide a safeguard for the protection of EU interests,** values and strategic priorities in standardisation activities linked to sensitive areas of sovereignty or security. This can in turn contribute to increase EU influence in international standardisation by ensuring that EU interests and values are first reflected in EU-driven standards and then projected internationally, in particular if the EU standardisation process becomes faster. Stakeholders generally support this measure, particularly where standardisation outcomes may have implications for strategic autonomy and critical technologies or infrastructure, such as electrical vehicle infrastructure or space technologies[246]. However, the effectiveness of the restriction would depend on the available expertise within the EU in the given technology and the ability of ESOs to exclude some of their non-EU/EEA experts[247].

This measure is not expected to generate additional direct costs for the Commission. ESOs could rely on the transparency obligations under Measure 1.8 to enforce the restrictions. Businesses are however uncertain about the impact of this measure on their organisations: 36 % of respondents in the targeted survey to industry organisations and companies (89 out of 247) consider it to be a benefit, while 27 % (67 out of 247) consider it to represent a cost[248].

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[241] As shown by the examples of workstreams of the HLF on DPP or Hydrogen. See Annex 12.
[242] Targeted survey to industry organisations and companies. 179 respondents out of 247.
[243] Impact Assessment Study; p. 64. See also the case study 5 on AI (Annex 15).
[244] According to the results of the targeted interviews with Annex III organisations, this measure should be complemented by long-term financial support to enable experts from civil society and SMEs' participation in international standardisation fora.
[245] Targeted survey to industry organisations and companies. 16 % of respondents identify it as a cost (40 respondents out of 247).
[246] See case study 3 on electric vehicle charging infrastructure and case study 4 on critical space technologies in Annex 15. 44 % (108 out of 247) of respondents to the targeted survey to industry organisations and companies indicated that the measure would strengthen EU presence and impact on international standardisation and 36 % (100 out of 247) that it would have no or small impact.
[247] Impact Assessment Study, p. 64-65.
[248] Targeted survey to industry organisations and companies.

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6.4.2. Policy Option 2: ESS centred on ESOs with new flexibilities

Measure 2.5: Possibility to derogate from 'international first' principle

The measure could also increase EU influence in ISOs by improving the negotiating positions of ESOs through the legal possibility for the EU not to incorporate an international standard as a hEN. The positive effects on EU strategic autonomy and competitiveness in key strategic technologies were highlighted in the case of the standard for electrical vehicle charging systems, where the technological solution agreed in IEC was not considered to reflect the EU ecosystem and where it was decided prioritise EU developed standards[249]. The measure would facilitate such decisions and make them more legally grounded.

Activating the measure could however lead to **partial decoupling from the international standardisation process,** with potential negative implications for market access, interoperability and cost efficiency of EU businesses. Industry organisations consider that such restrictions could lead to significant additional costs for EU producers active in international markets who would have to ensure compliance with both European and international standards[250]. Stakeholders, in particular CEN-CENELEC and NSBs, cautioned that any derogation should be limited to very specific cases and well-justified. The additional costs to the Commission to implement the measure is estimated at 1 FTE.

6.4.3. Policy Option 3: Open ESS managed by the Commission

Measure 3.5: End of the automatic 'international first' principle

This measure has similar effects as measure 2.5; it can have a positive impact on EU ability to implement strategic autonomy and could contribute to increase the EU's negotiating position in ISOs. However, stakeholders assess that it would lead **in practice to negative effects on the EU's influence in international standardisation**. Industry considers that it would isolate the EU, potentially leading to decoupling and a reduction in competitiveness through the additional costs incurred for EU businesses to develop separate products for the European and international markets[251]. Likewise, for ESOs and NSBs, the Vienna and Frankfurt agreements are a major driver of EU influence in ISOs and turning back on their automaticity would decrease such influence[252]. It is also unlikely that more requests addressed to alternative SDOs would increase EU influence, although alternative SDOs may have their own international agreements. Moreover, the implementation of the measure, and the *ad hoc* assessment of the benefits of applying the 'international first' principle for each request, would require additional resources from the Commission estimated at 2 FTEs.

6.5. Macro-economic impact of policy options

The implementation of each option impacts EU competitiveness, the functioning of the internal market and EU innovation performance. This section presents the main result of a macro-economic analysis examining the impact of the policy options (measured as a variation of the

[249] See Annex 15, case study 3. The possibility to derogate form the 'international first' principle was also advocated by stakeholders in case study 4 on critical space technology.
[250] Interviews with industry organisations and HAS consultants. In addition, 30 % of respondents of the targeted survey to industry associations (74 out of 247) expected opt-outs to lead to no or only a small impact, while 26 % (64 out of 247) expected a large or very large impact.
[251] Contributions to the Call for Evidence and position papers from the OPC.
[252] Contributions to the Call for Evidence and position papers from the OPC.

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available stock of hENs) on three dimensions capturing the general objectives of the initiative: EU GDP, innovation performance and trade performance. Methodology, assumptions and details are provided in Annex 4.

The **impact on GDP** would range between an additional EUR 0.88 billion for Option 1, EUR 0.98 billion for Option 2 and EUR 1.15 billion for Option 3[253], an overall marginal contribution to EU growth of less than 0.01% in all cases. All options contribute to EU competitiveness by fostering faster adoption and diffusion of hENs, thus decreasing transactions costs within the internal market. Option 2 can make a more decisive contribution to EU competitiveness by accelerating the availability of hENs in key strategic sectors essential to EU long term competitiveness, notably in the digital and clean technologies areas. Option 3 offers higher long-term competitiveness potential by allowing to rely on the most relevant SDOs for each hEN but incurs high implementation risks that can disrupt the functioning of the ESS and ultimately slow the delivery of hENs. All options will have a positive impact on SME competitiveness as SMEs are expected to benefit most of the improved availability of hENs. It is estimated that for all options, SMEs will capture around 78 % of savings in conformity assessment generated[254].

Innovation can be positively affected by the options due to the role of standardisation in technology transfer and market access[255]. However, the economic analysis did not find a correlation between an increased in stock of hENs and innovation performance[256]. Options 2 and 3 can contribute more to innovation by ensuring that hENs better reflect the state-of-the art and are developed faster in high-innovation sectors.

The options can also positively impact on **trade**. Standards play a pivotal role as a key non-tariff barrier under the WTO's Technical Barriers to Trade (TBT) Agreement and hENs can cut trade costs significantly[257]. The economic analysis finds a significant elasticity of 0.0632 on the stock of hENs, indicating that a hypothetical 10 % increase in the total stock of hENs would contribute to an increase of 0.632 % in overall exports (intra-EU and extra-EU)[258].

7. HOW DO THE OPTIONS COMPARE?

7.1. Effectiveness of the proposed policy options

The effectiveness of each policy option against the specific policy objectives is summarised in Table 2 below.

Table 2: Overview of the effectiveness of each policy option

[253] Impact assessment study, p. 70.
[254] See Annex 6. SMEs represent 99 % of the companies affected by the Options but on average develop 28 times less new models than large undertakings per year, thus requiring 28 times less conformity assessment.
[255] The Council Recommendation on the guiding principles for knowledge valorisation (EU) 2022/2415, the Commission Recommendation on the Code of practice on standardisation (EU) 2023/498 and the Oslo Manual recognises standardisation as an innovation activity, highlighting its role in spreading new technologies, fostering open, cross-industry collaboration and strengthening industry-academia cooperation.
[256] Impact assessment study, p. 70.
[257] International harmonised standards are estimated to have contributed up to 13 % of the growth in global trade. Journal of International Economics 137 (2022) 103619, Julia Schmidt/Walter Steingress: No double standards: Quantifying the impact of standard harmonization on trade.
[258] Impact assessment study, p. 70-71.

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Effectiveness of policy options against specific objectives	**Specific Objective 1 Increasing the responsiveness of the ESS**	**Specific Objective 2: Ensuring the sustainability of the ESS**	**Specific Objective 3 Consolidating EU influence in international standardisation**
Policy Option 1 Modernised ESOs monopoly	++	++	+
Policy Option 2 ESS centred on ESOs with new flexibilities	+++	++	++
Policy Option 3 Open ESS managed by the Commission	+++	-	+/-

Legend: +++ significant positive impact; ++ positive impact; + minor positive impact
+/- no or neutral impact; '- negative impact

All proposed options will significantly contribute to increasing the responsiveness of the ESS (Specific objective 1). The set of measures included in **Option 1** to accelerate the development of hENs will contribute to decreasing the average time to obtain a hEN from ESOs by 1 year (- 19 % compared to the baseline). **Option 2** will be more effective by adding flexibility for the EU to address standardisation requests to alternative SDOs. The additional impact on the average time to deliver a standard would however be limited as the flexibility would apply to only a few cases but can make an essential contribution to competitiveness and technological sovereignty in the cases where it will be used. Moreover, it also increases the incentives of ESOs to deliver hENs as they could face competition from other SDOs, increasing its overall effectiveness on responsiveness. **Option 3** is also highly effective as it allows the Union to choose the most relevant SDOs to deliver on each standardisation request, ensuring fast availability of quality hENs – although this depends on the actual ability of alternative SDOs to deliver hENs in line with their claimed standardisation practices, which has not yet been tested. The absolute magnitude of these effects remains sensitive to assumptions on time reduction and use of new flexibilities. However, this uncertainty does not affect the relative ranking of options under this objective, as the assumptions were applied consistently and conservatively across options.

As regards specific objective 2, **Option 1** is effective, principally because it is the less disruptive to the current functioning of the ESS. Improvement in ESOs' standardisation process will foster participation of all actors – industry and civil society organisations – in standardisation activities from the ESOs, which will retain the ability to finance their functioning and the planned improvements. **Option 2**, although introducing stronger requirements on free access to hENs, can also ensure the sustainability of the ESS from a legal and financial point of view and will foster the inclusiveness of the ESS by addressing the main gap in national inclusiveness. **Option 3** would have a negative impact on the sustainability of the ESS compared to the baseline as it will suppress the financial incentives from ESOs to deliver hENs and could have an adverse effect on participation of the industry into the process.

Policy Options 1 and 2 will be more effective than the baseline to consolidate EU influence in international standardisation (specific objective 3) but differ in how they balance coordination, flexibility and strategic control. **Option 1** represents the most incremental approach, focusing on improved coordination and targeted safeguards to increase the participation of all EU stakeholders in international standardisation. **Option 2** introduces greater flexibility by

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allowing targeted derogation from the 'international first' principle, strengthening the EU ability to protect strategic interests. **Option 3** has overall a neutral effect on the objective. It introduces the possibility to align EU and international standards on a case-by-case basis, increasing strategic control but decreasing the alignment between EU and international standards, in turn limiting EU influence in international fora.

7.2. Costs and benefits of the proposed policy options

The summary of costs and benefits associated with each option as quantified where possible in Section 6 is presented in Table 3 below, supported by analyses in Annex 4.

Table 3: Costs and benefits of each policy option[259]

Costs and benefits under each policy option by main stakeholders affected (per	**Policy Option 1 Modernised ESOs monopoly**		**Policy Option 2 ESS centred on ESOs with new flexibilities**		**Policy Option 3 Open ESS managed by the Commission**	
	Benefits	**Costs**	**Benefits**	**Costs**	**Benefits**	**Costs**
Industry & companies	EUR 265 million	0	EUR 325 million	EUR 10.5 million	EUR 378 million	EUR 25 million*
ESOs and NSBs	n.a.	EUR 2.2 million	EUR 6 million	EUR 32.9 million	EUR 10 million	EUR 49 million
Annex III and civil society organisations	EUR 1.2 million	0	EUR 1.9 million	0	EUR 0.4 million	0
European Commission	n.a.	EUR 0.5 million	n.a.	EUR 1.5 million	n.a.	EUR 8.1 million**
Overall efficiency	++		++		+/-	

Legend: ++ very efficient; + efficient ; +/- neutral; - inefficient; n.a. non applicable
* Not including additional costs not quantifiable linked to possible divergence between EU and international standards
** Excluding potential translation costs linked to publication of hEN in the OJEU

Building on the existing ESS whose cost-efficiency was highlighted in the Evaluation, **Option 1** will generate **important savings for EU businesses with limited additional resources** from NSBs and the Commission, making it very efficient in terms of financial benefits. However, non-monetary benefits, such as improved inclusiveness, the increased EU influence in international standardisation and stronger legal certainty regarding access to standards, which cannot be quantified, are relatively limited due to the less-ambitious nature of the measures proposed.

Option 2, also largely relying on the current ESS, is also very efficient. Potential **benefits for businesses are larger than in Option 1** (by EUR 66.7 million per year) through additional savings from a more responsive system, for an additional cost of EUR 44.9 million (*i.e.* a net financial gain of EUR 21.8 million compared to Option 1). The option incurs additional net costs for the Commission and NSBs to implement the Expert Centre and increase inclusiveness at national level, as well as costs linked to participation in other SDOs for businesses. The option involves **important monetary transfers within the ESS.** The free access to hENs is a transfer of resources from ESOs and NSBs to the end-users of standards (businesses). These transfers do not affect the overall efficiency of the option, which is however dependent on the ability of ESOs to generate new revenues to absorb the loss of hENs sales. The cost-benefit

[259] Details of the calculations and of the transfer of costs across actors are available in Table 4.3 Annex 4.

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ratio of monetary gains for Option 2 is lower than for Option 1 (99 for Option 1 versus 7 for Option 2). However, non-monetary (and non-quantifiable) gains related to stakeholder inclusiveness into the standardisation process, legal certainty regarding access to standards and the EU's influence in international standardisation are larger for Option 2 than for Option 1. As such, Option 2 can be considered as efficient as Option 1: Option 1 incurs lower costs but provide less overall benefits related to the policy objectives, while Option 2 is more expensive but go further in achieving the policy objectives.

The impacts of **Option 3** on the ESS are of a different nature. This option can generate **important benefits** for the industry through a more responsive system based on both ESOs and alternative SDOs and through free access to hENs published in the OJEU. However, the increased responsiveness generates costs from the Commission to manage this new approach to EU standardisation, while the publication in the OJEU limits the ability of the ESOs and NSBs to create value from hENs. This leads to **net additional costs** for the entire system (and not only transfers from one stakeholder to another) that make this option the least efficient. There are also extra costs for industry linked to participation in multiple SDOs as well as costs linked to the increased divergence between EU and international standards.

7.3. Coherence and proportionality

The revision of the Standardisation Regulation will take place in coordination with the upcoming EPA, a comprehensive legislative initiative to modernise the product safety and compliance framework across the internal market. Each policy option has been designed to ensure **coherence** with the EPA and its main objective of improving the competitiveness of the internal market, by ensuring that a sustainable, responsive and internationally relevant ESS delivers the hENs necessary to the functioning and competitiveness of the internal market. **Option 1** is fully coherent with the reform of the NLF by strengthening the ESOs' ability to deliver the hENs needed for the efficient implementation of sectoral legislation. **Option 2** is even more coherent with EU law and policy objectives, as it introduces better conditions for accessing hENs, facilitate the delivery of hENs in new technology areas covered by the NLF and allow to implement strategic autonomy in European standardisation when necessary. **Option 3** is also overall coherent with EU law but can lead to disruption in the functioning of the NLF by halting the long-term partnership with ESOs to support its implementation. It will also create uncertainties for EU companies trading with international partners.

As regards **proportionality**, **Options 1 and 2** are proportionate as they incur limited additional costs compared to the baseline while being effective to reach the specific objectives. The proportionality of **Option 3** is more uncertain: it involves significant changes to the functioning of the ESS that come with important implementation risks which can affect both the functioning of the internal market and the sustainability of the ESS. These costs and risks are not necessary to achieve the objectives pursued.

7.4. Summary of assessment

Stakeholders express general support for Option 1 as they assess that it will bring significant improvements to the ESS compared to the baseline while building on its existing strengths. **Stakeholders' views are more mixed towards Option 2**. Industry and companies express some support for this option as they see benefits in the increased responsiveness of the system. While the views on the possibility for the Commission to address requests to alternative SDOs

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are mixed[260], the specific sectors potentially most concerned by such a possibility consider it beneficial, as highlighted by the case studies. Annex III organisation and representatives of civil society interest generally support Option 2 as long as the use of alternative SDOs does not decrease the inclusiveness of standardisation. ESOs and NSBs prefer Option 1 as it would have less impact on their current business model. **No stakeholder group expressly supports Option 3**, albeit for different reasons. Businesses fear that it will disrupt the delivery of hENs and entail too much risk on the activities of ESOs. They also oppose the possible divergence from international standardisation that an *ad hoc* application of the 'international first' principle could lead to. Annex III organisations also oppose this option as it would affect their ability to participate to standardisation. ESOs and NSBs are the most strongly opposed, as it would require an overhaul of their financing structure.

Table 4: Stakeholders' support by Policy Option

Summary of stakeholders' support for policy options	**Businesses**	**ESOs/ NSBs**	**Annex III organisations and civil society**
Policy Option 1 Modernised ESOs monopoly	++	++	++
Policy Option 2 ESS centred on ESOs with new flexibilities	+	-	+
Policy Option 3 Open ESS managed by the Commission	-	--	-

Legend: ++ strongly support; + support; +/- neutral position; - oppose; -- strongly oppose

Option 1 would have a strong positive impact on the functioning of the internal market, by increasing the timely availability of hENs. **Option 2** can have a stronger impact than Option 1 in supporting the EU competitiveness agenda, in particular in new strategic technologies thanks to the flexibility to address requests to alternative SDOs. Both options are efficient, although Option 2 incurs more costs and more changes to the ESS. The assessment concludes that **Option 3** is both the less effective and efficient option.

Table 5 below summarises the assessment and the comparison of Options, providing an overview of their effectiveness, efficiency, coherence with EU law and proportionality.

Table 5: Assessment overview

[260] 37% of all respondents (196 out of 588) in the OPC agreed that the ESS should be opened to allow other organisations or consortia to respond to specific standardisation requests alongside the recognised ESOs, while 49 % disagreed (288 out of 588) and 14 % were neutral or did not know (82 out of 588).

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Overall assessment	Effectiveness	Efficiency	Coherence	Proportionality
Policy Option 1 Modernised ESOs monopoly	++	++	+	++
Policy Option 2 ESS centred on ESOs with new flexibilities	+++	++	++	++
Policy Option 3 Open ESS managed by the Commission	+	+/-	+/-	-

Legend: +++ very positive impact; ++ positive impact ; + moderate positive impact
+/-neutral impact; '- negative impact; -- very negative impact

8. PREFERRED OPTION

8.1. Summary of preferred option

The preferred option is Option 2: an ESS centred on ESOs with new flexibility. It retains the benefits of the current ESS and brings significant improvements to its functioning, while creating the possibility to leverage alternative SDOs when they could contribute faster and more quality hENs than the ESOs.

Both Policy Options 1 and 2 can make a significant contribution to the specific and general objectives but Option 2 features **three important advantages**: it better supports **EU competitiveness and technological sovereignty** by enabling access to state-of-the-art expertise in critical technologies; it improves ESO performance by introducing **a degree of competitive pressure**; and it is more **future-proof**, ensuring free and unrestricted access to hENs and allowing the system to adapt if ESOs modify their sectoral coverage or new SDOs emerge as leaders in specific fields.

The key features of the preferred option are:

- An **ESS centred on ESOs**, who will retain the responsibility to deliver most of the hENs to the Commission, under a simplified, more efficient and inclusive process.
- The possibility for the Commission to address standardisation requests to **alternative SDOs**, to leverage the latest state-of-the-art expertise in key strategic technologies.
- **Free and unrestricted access to hENs**, through a central repository managed by the ESOs or the Commission.
- **Strengthened EU coordination in international standardisation**, with targeted flexibilities to ensure its strategic autonomy.
- An **EU Expert Centre** led by a CSO to improve Commission oversight on the ESS.

8.2. REFIT (simplification and improved efficiency)

The Evaluation of the Standardisation Regulation highlighted the potential and need for simplification of the processes to deliver hENs. The preferred policy option will bring simplification and improved efficiency through the following means:

- The **faster availability of hENs** will significantly reduce businesses' compliance costs and facilitate the conformity assessment of their products and services.

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- The **central repository for hENs will simplify access to hENs for all stakeholders of the ESS**, not only reducing costs for users through free access but also facilitating their consultation and use.
- The **new obligations on NSBs for including civil society organisations and SMEs** will simplify the participation of these stakeholders to the standardisation process, notably by reducing their participation costs.
- The **simplification measures introduced in the legal process to adopt standardisation requests and reference hENs** will accelerate the regulatory process for adopting hENs.
- The **improved organisation within the Commission through the Experts' Centre**, coupled with the on-going digitalisation of the exchanges between ESOs and the Commission, will create efficiencies and contribute to improve the quality and efficiency of reporting and monitoring activities.

8.3. Application of the 'one in, one out' approach

The preferred option complies with the 'one-in, one-out' (OIOO) principle by ensuring that newly introduced administrative and other compliance costs are more than offset by reductions in existing burdens. Overall, the preferred option delivers **a substantial reduction in compliance costs for businesses of EUR 295 million**, benefitting from savings from earlier availability of hENs, while not incurring any additional administrative costs compared to the baseline.

The preferred option increases **administrative costs for ESOs** through the transparency register but does not create additional administrative costs linked to reporting obligations due to efficiencies expected from the on-going digitalisation process. These costs are estimated at EUR 1.0 million for ESOs and NSBs and are proportionate to the scale of economic benefits and improvements in the functioning of the internal market. The preferred option requires an increase in resources of the Commission for its efficient implementation with the creation of the Expert Centre, estimated at EUR 1.5 million additional administrative costs.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The **improved monitoring of the implementation** of the Standardisation Regulation by the Commission is a key dimension of this initiative. The preferred option plans the introduction of tools and mechanisms to improve transparency and increase accountability of the ESS for all stakeholders. The Commission will monitor the improvements in the responsiveness of the ESS by setting up key performance indicators on **speed**, **timeliness**, **quality and flexibility.** Monitoring of the sustainability of the ESS will help assess the ability and incentives of stakeholders to engage in standardisation activities. The Commission will also monitor **effective access to hENs**, **engagement of ESOs, participation of experts** as well as **inclusiveness**. The overall EU influence in international standardisation will be monitored through: **EU involvement in ISOs**, **ability of the EU to ensure strategic autonomy** and **actual influence in ISOs**. The monitoring will mainly rely on data reported by the ESOs and SDOs through the eNorm platform.

The Commission will conduct an evaluation of the revised Standardisation Regulation 5 years after its entry into force, based on indicators from Table 6.

Table 6: Planned indicators for monitoring the impact of the initiative

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Objective	Indicators
Improving the responsiveness of the ESS	• **Speed and timeliness**: average duration for referencing a hEN, for each step of the process, and share of hEN available on time to support Union legislation • **Quality**: number of offered hEN rejected by the Commission • **Flexibility**: share of hENs involving alternative SDOs and number of CS adopted
Ensuring a financially viable and inclusive ESS	• **Effective access**: number of consultations of hENs in the central repository • **Engagement of ESOs**: share of requests rejected by the ESOs • **Participation of experts and inclusiveness**: total number of experts engaged in EU standardisation activities, including SME, civil society and R&I experts
EU influence on international standardisation	• **EU influence in ISOs**: number of TC in ISO/IEC chaired by the EU and number of international standards influenced by EU • **Ability to ensure strategic autonomy**: number of requests restricted to EU/EEA, number of derogations to the 'international first' principle

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ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

Lead DG: DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), Directorate: H: Construction, Machinery and Market Surveillance.

This impact assessment corresponds to the initiative with the Decide reference PLAN/2024/2488, revision of the EU Standardisation Regulation.

This initiative is also part of the 2026 Commission Work Programme, under the header 'Single Market', with the Commission's proposal planned by Q3 2026.

2. ORGANISATION AND TIMING

The call for evidence feedback period ran from 23 June 2025 until 21 July 2025.

The public consultation period ran from 24 September 2025 until 17 December 2025.

An inter-service coordination group (ISCG) was convened and chaired by DG GROW. The following Directorates-General participated: CLIMA, CNECT, COMP, DEFIS, DGT, DIGIT, ENER, ENEST, FISMA, HOME, JUST, JRC, RTD, SANTE, SG, TRADE. The ISCG met 7 times. The last meeting on the final draft impact assessment report was held on 11 May 2026.

3. CONSULTATION OF THE RSB

The RSB was consulted in an informal upstream meeting on 8 September 2025.

This impact assessment was submitted to the RSB on 20 May 2026.

The meeting with the RSB took place on 17 June 2026.

The RSB provided an overall positive opinion on 19 June 2026. Following the opinion of the RSB, changes were made to the IA to reflect the recommendations of the Board. A summary of the RSB's recommendations and how these have been addressed is provided below.

Summary of the RSB findings and how the comments have been addressed:

Opinion of the RSB	How the comments have been addressed
Key issue 1 The report does not sufficiently analyse how the participation of stakeholders in the standardisation process affects the quality of the EU harmonised standards and their timely delivery. *What to improve:*	
(1) The report should draw on additional evidence to analyse the impact of stakeholder participation from both SMEs as well as from civil society organisations on the quality and timely delivery of standards.	(1) The revised report expands the analysis on "Problem 2 – Lack of balanced stakeholder participation challenges the quality of standards" by referring to existing scientific literature on the link between inclusiveness and

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	standard quality and to the results of the stakeholders' consultation.
Key issue 2 The second specific objective is not defined sufficiently clearly to address the identified problems, including the issue of balanced stakeholder participation. *What to improve:*	
(2) The report should better explain how the second specific objective relates to the identified problems. The objective should be redefined to better reflect that it aims to ensure a balanced stakeholder representation, inclusive access to harmonised standards and a legally and financially viable standardisation system providing EU harmonised standards.	(2) The revised report redefines Specific Objective 2 to better reflect that it covers both the sustainability of the ESS in the financial sense and its ability to mobilise stakeholders' participation. The description of the objective also clarifies the interaction between access to standards, financial viability and inclusiveness and why these dimensions are covered under the same specific objective.
Key issue 3 The report does not describe in sufficient detail some of the policy measures making the assessment of their impacts uncertain. The analysis of efficiency is not sufficiently clear to inform the comparison of options. *What to improve:*	
(3) The report should provide, to the extent possible, more details on the policy measures to be implemented such as requirements for stakeholder participation or approach to deadlines and the possible costs for stakeholders. The report should be clearer and comprehensive about the costs for all concerned stakeholders, including the EU budget.	(3) The revised report expands the description of policy options, based on Annex 10, and strives to assess impacts on costs for all stakeholders for measures where it is possible, including costs that are transfers from one stakeholder group to another, as illustrated in tables 4.3 of Annex 4.
(4) Building on a more comprehensive assessment of the costs to all stakeholders, the efficiency analysis should follow the standard methodology, i.e. be based on societal benefit cost ratio. In case other approaches to efficiency assessment are used in addition to societal benefit cost ratio, the report should explain the methodology.	(4) The revised report includes a more in-depth analysis of efficiency of policy option based on two metrics for efficiency: benefit/costs ratio and net social benefit. This allows to refine the assessment of efficiency and to assess Option 2 and Option 1 as similarly efficient.
(5) The limitations and uncertainties related to the analysis of the problems and the impacts need to be further clarified as well as the extent to which they affect the comparison of options.	(5) The revised report adds a liminary section for the assessment of all specific objectives to highlight the key limitations in the methodology employed and clarifies that these limitations do not affect the relative comparison of options.

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4. EVIDENCE, SOURCES AND QUALITY

The Evaluation of the Standardisation Regulation[261] identified the key areas for the revision. It was supported by a study conducted by an external contractor[262].

This Impact Assessment is also supported by a new study[263] undertaken by an external contractor, who carried out dozens of interviews, analysed data from both public and targeted consultations and conducted desk research. The targeted consultations include an SME Workshop (see Annex 6), an NSBs Validation Workshop and a meeting with the Committee on Standards. More details on the consultation process are provided in Annex II. The High-Level Forum on European Standardisation was held on 19 March 2026 to facilitate policy discussions on the revision, while technical meetings with the High-Level Forum Sherpas were organised to discuss, consult on and provide updates regarding the process.

Annex 4 provides more details on the analytical methods to collect the evidence supporting this impact assessment.

[261] Evaluation of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation.

[262] Evaluation Study of the regulation (EU) 1025/2012 on European standardisation: https://op.europa.eu/publication-detail/-/publication/57cb8a80-4fe4-11f0-a9d0-01aa75ed71a1.

[263] Impact Assessment supporting Study accompanying the revision of the EU standardisation Regulation EU 1025/2012, Intellera Consulting SpA, Fraunhofer ISI.

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ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

1. CONSULTATION ACTIVITIES

The consultation strategy included a range of public and targeted activities designed to triangulate the findings with other sources of information. The purpose was to get stakeholder feedback on the revision of Regulation (EU) No 1025/2012, hereafter the Standardisation Regulation, notably on the problem definition, the possible policy options and possible impacts of those on the stakeholders. It was particularly important to gather views and data of stakeholders that are often under-represented in the standardisation process, e.g. SMEs.

The consultation activities were conducted between June 2025 and May 2026, and included:

- The call for evidence, launched on the Have your say portal between 23 June 2025 and 21 July 2025.
- The open public consultation (OPC), opened from 24 September to 17 December 2025.
- One targeted online survey for industry organisations and companies, including SMEs, to gather specific feedback on costs and benefits to be expected from the different options.
- In-depth interviews with 17 NSBs/NCs/NSOs, to gather quantitative details on the potential impact of policy options on revenues, costs, and business models.
- In-depth interviews with CEN-CENELEC and five EU industry organisations to fine-tune quantitative analysis of impacts expected for ESOs, NSBs/NCs/NSOs and companies.
- In-depth interviews with all four Annex III organisations to assess the impact of policy options on the representation of societal interests and SMEs in European and international standardisation.
- In-depth interviews with relevant DGs of the European Commission to gather a sector-specific assessment.
- Five workshops with (i) SMEs and their EU representative organisations, (ii) HLF sherpa sub-group and (iii) NSBs/NCs/NSOs.

Additional interviews were carried out between April and May 2026 to gather quantitative and qualitative insights for the five sectoral case studies detailed in Annex 7.

The OPC and the targeted surveys were conducted online, through the EU Survey Tool[264], and they were widely disseminated among stakeholders using different channels, from direct emails to engagement of relevant multipliers (EU industry organisations, ESOs, SBS, and the European Enterprises Network).

[264] https://ec.europa.eu/eusurvey/home/welcome.

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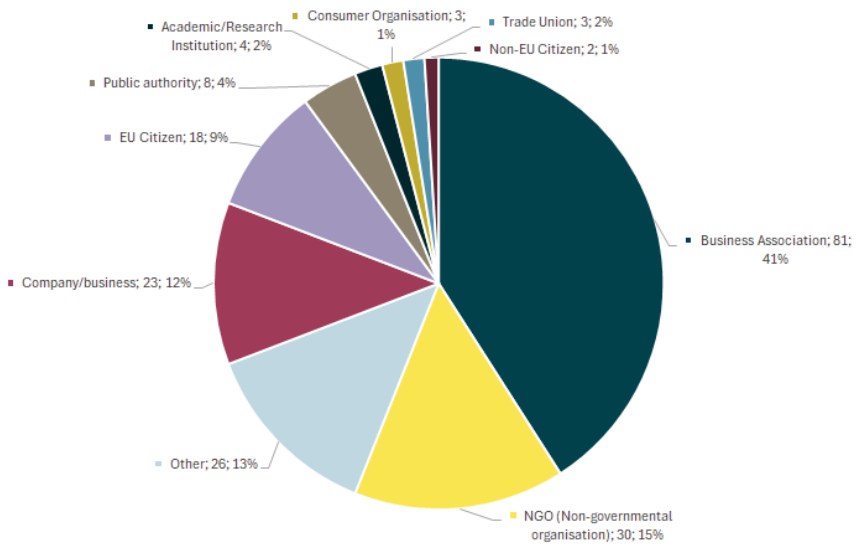
The dissemination activities were regularly monitored, and the overall strategy was constantly updated to fill gaps emerging both in terms of geographical coverage and representativeness of stakeholder groups. All interviews were conducted virtually.

1.1. Call for evidence

A call for evidence was launched on the Have your say portal between 23 June 2025 and 21 July 2025. A total of 198 valid feedback[265] was received from 24 countries, with the highest participation coming from Belgium (30 %, 59 responses), Germany (18 %, 36 responses), France (10 %, 20 responses), and Spain (6 %, 12 responses). The call for evidence also received responses from representatives outside EEA, including Mexico, Türkiye, United Kingdom.

Business associations accounted for the largest share of participants, with a total of 81 replies (41 %). NGOs (non-governmental organisations) represented 15 % of respondents (30 replies), followed by 12 % (23 replies) of companies/businesses, 9 % (18 replies) of EU citizens, 4 % (8 replies) of public authorities, 2 % (4 replies) of academic/research institutions, 2 % (3 replies) of consumer organisations, 2 % (3 replies) of trade unions, 1 % (2 replies) of non-EU citizens. A further 13 % (26 replies) of respondents selected "other" as stakeholder category. The figure below summarises the stakeholder categories of respondents.

Figure 1-1 Distribution of responses by stakeholder groups



1.2. Open public consultation (OPC)

The OPC on the proposal for the revision of the Standardisation Regulation took place from 24 September to 17 December 2025. The consultation aimed to collect relevant evidence on the key challenges and opportunities for the revision, including the policy options under consideration and their impacts.

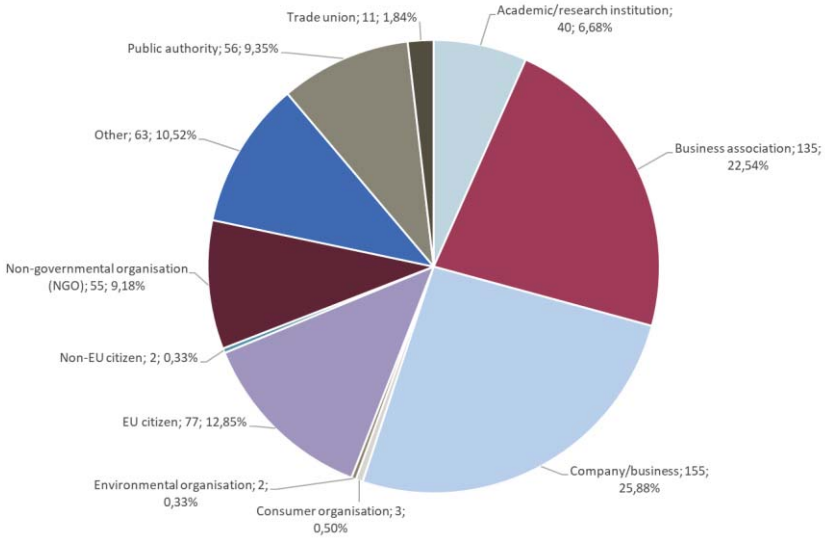
599 valid replies were submitted to the public consultation from 32 different countries. Respondents were distributed across 11 stakeholder groups.

[265] Total feedback received amount at 200, but 2 duplicates were detected.

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Businesses represented the largest share of participants, for a total of 135 business associations and 155 companies. The number of SMEs amounted to 12 % (69 replies), where 21 were small enterprises (10 to 49 employees) and 25 were micro-enterprises (1 to 9 employees). 13 % of respondents were citizens (79 replies; 77 from EU countries and 2 from non-EU countries). All the four organisations recognised in Annex III of the Standardisation Regulation as well as all three European Standardisation Organisations (ESOs) participated to the survey. The figure below summarises the stakeholder category of respondents.

Figure 1-2 Distribution of responses by stakeholders groups



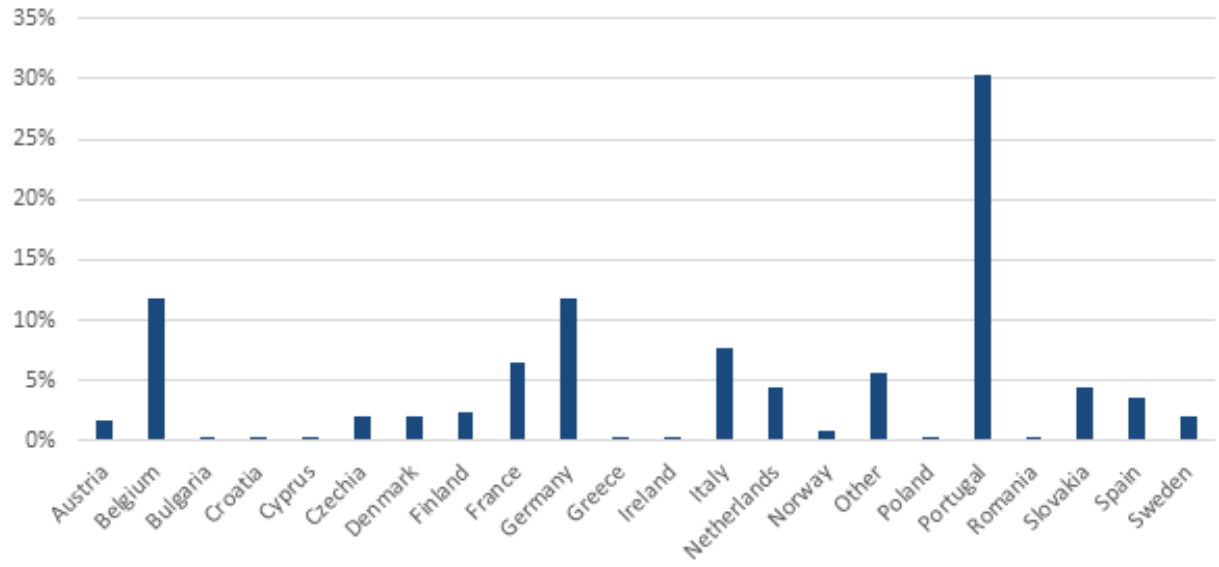
1.3. Targeted surveys (TS)

1.3.1. Industry organisations and companies

A total of 247 responses were received through the targeted survey with industry organisations and companies, 67 % (165 out of 247) from companies and 33 % (82 out of 247) from industry associations. Respondents covered 26 countries, mainly in the EEA area. The geographical distribution of responses varied across countries: Portugal accounted for the highest share, with 30 % of total responses, followed by Germany and Belgium, each accounting for 12 %. The remaining countries each represented between 2 % and 8 % of total responses. This distribution is presented in the chart below.

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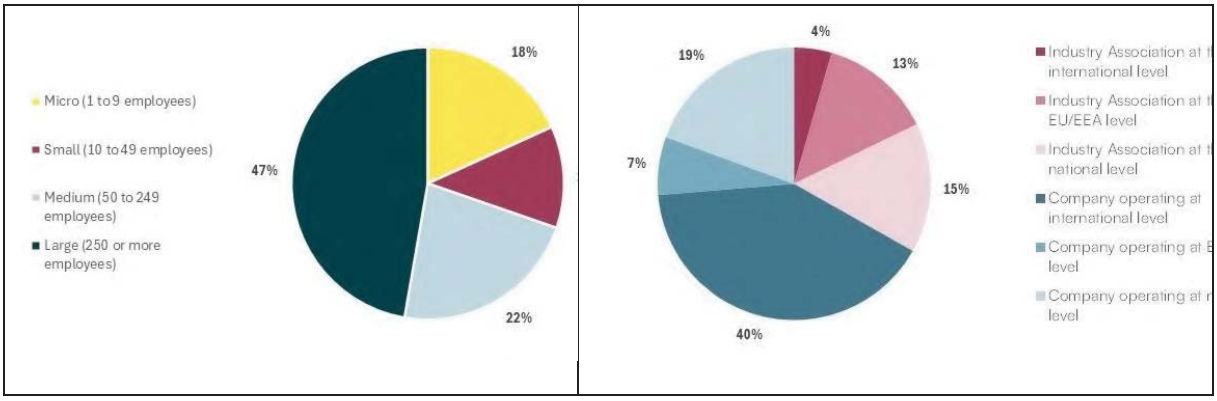
Figure 1-3 Geographical distribution of industry TS participants



Among the companies replying to the survey, 53 % (87 out of 165) were SMEs (18 % micro, 12 % small, and 22 % medium enterprises), and 47 % (78 out of 165) were large enterprises.

Respondents also differed in terms of their level of operation, 35 % operate at national level, 20 % at the EU/EEA level, 45 % at the international level.

Figure Size distribution of TS participants by company (a) and operational level distribution of industry TS participants (b)



1.3.2. National standardisation bodies, national committees and national standardisation organisations (NSBs/NCs/NSOs)

A total of 37 responses were received through the survey, representing 25 countries, mainly in the EEA area. Regarding ESO membership, since NSBs may hold memberships in more than one ESO, the survey received contributions from 26 CEN members, 25 CENELEC members, and 19 ETSI members. CEN-CENELEC affiliates participated in the survey, including NSBs from Ukraine and the Republica of Moldova.

1.4. Workshops

The following workshops have been conducted:

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- Two workshops with the HLF sherpa sub-group, to discuss policy options and their potential implications with Member States representatives and ESOs (13 October 2025) and to validate the analysis considering the feedback of Members States and ESOs (20 April 2026.

- Two workshops with NSBs/NCs/NSOs, to gather specific feedback on costs and benefits to be expected from the different options (21 November 2025) and to validate the analysis considering the specific costs and benefits for NSBs/NCs/NSOs (24 April 2026).

- One workshop with SMEs and their EU representative organisations, to validate the analysis considering the specific costs and benefits on SMEs (27 March 2026).

2. MAIN RESULTS OF CONSULTATIONS

The stakeholder groups consulted show different levels of support towards the different policy options, which is summarized in the following table.

Policy option	Industry organisations and companies	*of which SMEs and their representatives*	European and National standardisation organisations	Annex III organisations and societal stakeholders
Policy option 1	++	++	+	++
Policy option 2	+	+	-	+
Policy option 3	-	-	--	-

Legend: "++" strong support", "+" support, "0" neutral, "-" opposition, "--" strong opposition

All stakeholder groups expressed strong support for Policy Option 1, as they expect it will bring significant benefits to the ESS compared to the baseline, without hampering the current strengths of the public-private partnership between the Commission and the ESOs.

Stakeholders' views are more mixed towards Policy Option 2. ESOs and NSBs oppose both (i) the possibility for the Commission to address requests to alternative SDOs, and (ii) the free access to hENs. This is particularly the case for the NSBs that rely mostly on sales of hENs to finance their activities and to organise the contribution of their national stakeholders to the standardisation process. Industry representatives and businesses express some support for Option 2 as they see benefits in the increased responsiveness of the system. Annex III organisations and representatives of societal stakeholders generally support Option 2 provided that the current guarantees regarding inclusiveness are maintained, including when other SDOs are involved.

No stakeholder group explicitly supported Policy Option 3 over the other options. ESOs and NSBs were strongly opposed to Option 3 in what regards the open selection of SDOs for standardisation requests while industry and business associations were more nuanced on the

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impact of such measure, ESOs and NSBs and industry generally oppose the publication of hENs in the OJEU as it would strongly challenge the financial sustainability of the ESS. They also oppose the end of the automatic 'international first' principle as it would isolate the ESS from international standardisation processes. Annex III organisations also oppose this option as it would affect their ability to participate in the standardisation process.

The detailed analysis of stakeholders' feedback is provided here below by objective and option.

2.1. SO1: increase responsiveness of the ESS

PO 1: modernised ESO's monopoly

Industry organisations and companies support the measures proposed to increase the responsiveness of the ESS under Policy Option 1. More specifically:

- In the targeted survey to industry organisations and companies, most respondents indicated that the use of a technical specification developed by the ESOs for temporary presumption of conformity until harmonised standard is ready would contribute to accelerating the standardisation process, to a moderate (28 %, 69 out of 247), large (30 %, 73 out of 247), or very large (18 %, 44 out of 247) extent[266]. In line with this, the impact of this measure was also assessed as moderately (31 %, 77 out of 247) or highly (25 %, 61 out of 247) beneficial to respondents' organisations. This is in line with the views already expressed in the OPC where the use of previous editions of standards and of technical specifications developed by the ESOs or the use of European Agile Specifications (EAS)[267] received a broad support.

- This position is also confirmed by SMEs[268]. Specifically, most SMEs participating in the targeted survey to industry organisations and companies evaluated the use of technical specifications developed by the ESOs for temporary presumption of conformity until harmonised standard to be effective, to a moderate (28 %, 41 out of 148), large (28 %, 42 out of 148), or very large (20 %, 29 out of 148) extent, in streamlining the development of standards. Moreover, the majority of respondents also recognised this measure to be moderately (24 %, 36 out of 148) or highly (30 %, 45 out of 148) beneficial to their organisation.

- Similar support was shown for the measure of using existing standards when the ESOs cannot deliver. Overall, most respondents to the targeted survey to industry organisations and companies agreed with the measure, to a moderate (28 %, 68 out of 247), large (27 %, 67 out of 247), or very large (20 %, 50 out of 247) extent, and

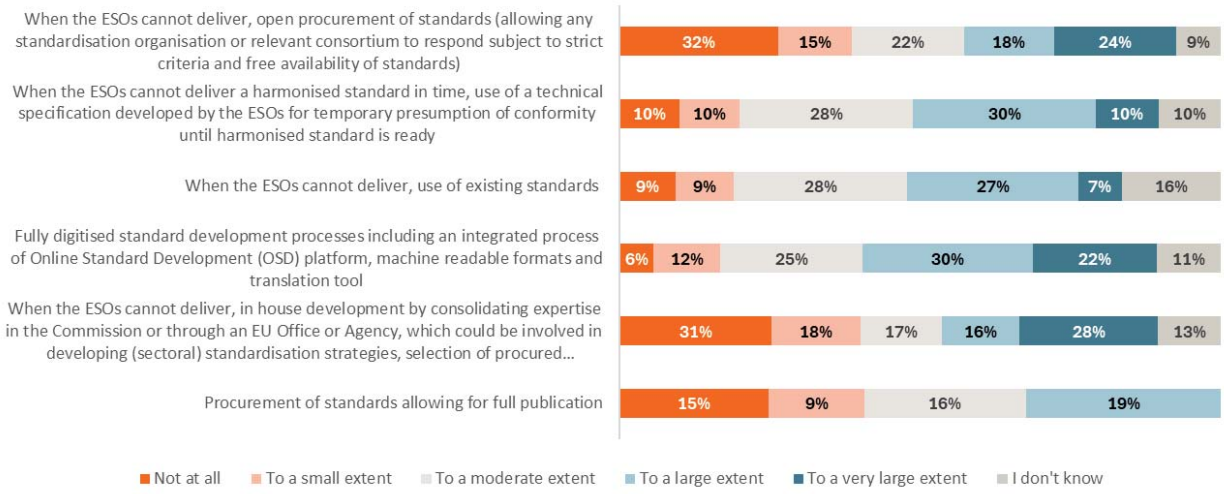
[266] Targeted survey to industry organisations and companies (*Q19: To what extent do you believe that these measures will support achieving the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 247.
[267] Contributions from the OPC, sorted by industry and companies (*Q9: What measures could be implemented when there are no harmonised standards or when such standards are delayed or unavailable at the time of applicability of the legislation they are supporting? For example: common specifications, interim solutions, use of previous standards*). Sample size, N=320.
[268] Targeted survey to industry organisations and companies – SMEs (*Q19: To what extent do you believe that these measures will support achieving the objective of simplifying and accelerating the development of high-quality standards?; Q21: Please indicate the extent to which the measures listed below impact your company*). Sample size, N = 148.

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assessed it as moderately (28 %, 70 out of 247) or highly beneficial (28 %, 70 out of 247) to their organisation.

- Among SMEs replying to the to the targeted survey to industry organisations and companies, 79 % of respondents considered this measure positive to accelerate the development of standards to a moderate (32 %, 48 out of 148), large (25 %, 37 out of 148), or very large (22 %, 32 out of 148) extent. At the same time, the majority of SME respondents to the survey considered the use of existing standards as moderately (30 %, 45 out of 148) or highly (28 %, 41 out of 148) beneficial for their organisation[269].

Figure 2-1 Q19: To what extent do you believe that these measures will support achieving the objective of simplifying and accelerating the development of high-quality standards? Sample size=247



Source: Targeted survey to industry organisations and companies

- In the targeted survey to industry organisations and companies, most respondents indicated that introducing legal deadlines and strengthen ESO obligations, including monitoring and KPIs would help to a moderate (26 %, 25 out of 247), large (22 %, 55 out of 247), or very large extent (10 %, 25 out of 247) to speed up the development of high-quality standards. In addition, several respondents considered this measure to be moderately (25 %, 61 out of 247) or highly (15 %, 36 out of 247) beneficial to their company[270].

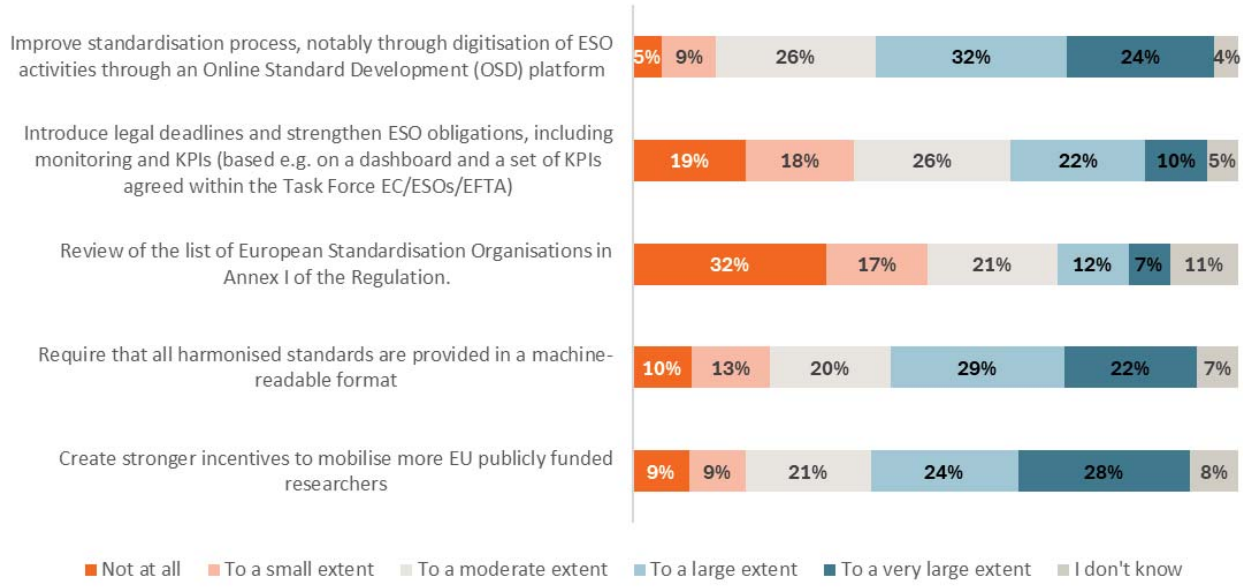
- Respondents to the targeted survey to industry organisations and companies were also in favour of the digitalisation of the standardisation process through machine-readable format hENs and the use of an Online Standards Development (OSD) platform, considering that it would make a positive contribution to simplifying and accelerating

[269] Targeted survey to industry organisations and companies – SMEs (*Q19: To what extent do you believe that these measures will support achieving the objective of simplifying and accelerating the development of high-quality standards?; Q21: Please indicate the extent to which the measures listed below impact your company*). Sample size, N = 148.
[270] Targeted survey to industry organisations and companies (*Q15: To what extent do you believe that this measure will support achieving the objective of simplifying and accelerating the development of high-quality standards?; Q17: Please indicate the extent to which the measures listed below impact your company*). Sample size, N=247.

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the development of high-quality standards.[271] In particular, most respondents indicated that requiring all hENs to be provided in a machine-readable format would contribute to the objective to a moderate (20 %, 49 out of 247), large (29 %, 71 out of 247), or very large (22 %, 54 out of 247) extent[272], At the same time, 82 % of respondents reported the same for the digitalisation of ESO activities through an OSD platform. Overall, most respondents considered that a fully digitalised standards-development process, including an integrated OSD platform, machine-readable formats, and translation tools, would contribute to a moderate (25 %, 62 out of 247), large (30 %, 74 out of 247) or very large (22 %, 54 out of 247) extent. However, a full digitalised standardisation process, despite being reported to speed up the standard development, was perceived to be costly by 41 % of respondents (102 out of 247).

Figure 2-2 Q15: To what extent do you believe that this measure will support achieving the objective of simplifying and accelerating the development of high-quality standards? Sample size=247



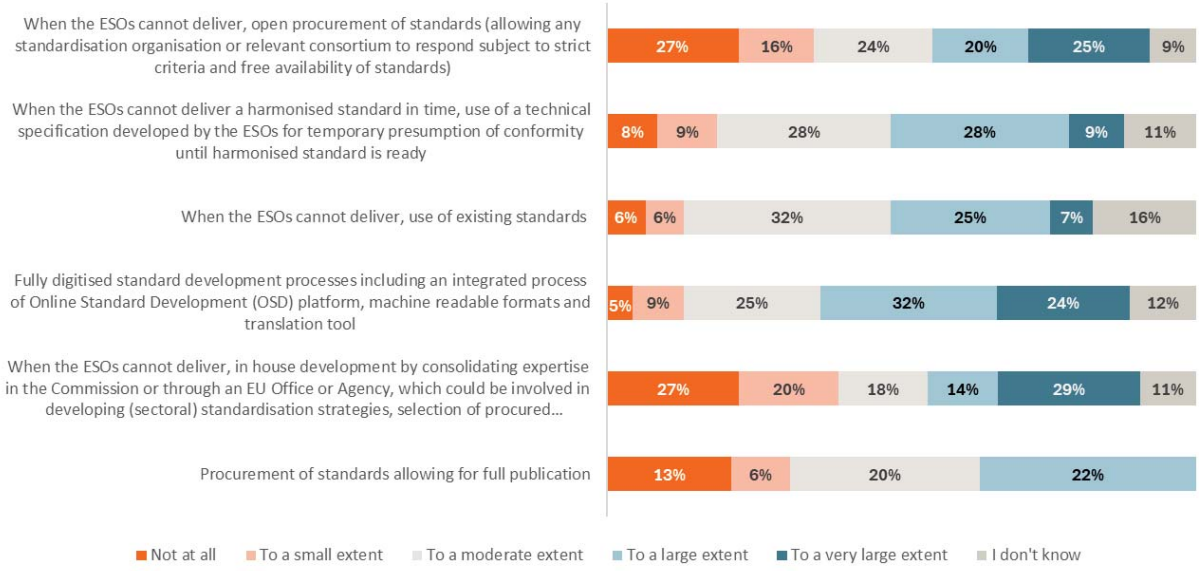
Source: Targeted survey to industry organisations and companies

- Some concerns have been raised about the introduction of legal deadlines and stronger ESO obligations - including monitoring and KPIs: 37 % of SMEs participating in the targeted survey to industry organisations and companies perceived its impact as a benefit, while 31 % regarded it as a cost[273].

[271] Targeted survey to industry organisations and companies (*To what extent do you believe that this measure will support achieving the objective of simplifying and accelerating the development of high-quality standards?; Please indicate the extent to which the measures listed below impact your company*). Sample size, N=247.
[272] Targeted survey to industry organisations and companies (*To what extent do you believe that this measure will support achieving the objective of simplifying and accelerating the development of high-quality standards?; Please indicate the extent to which the measures listed below impact your company*). Sample size, N=247.
[273] Targeted survey to industry and companies – SMEs (*Q17: Please indicate the extent to which the measures listed below impact your company*). Sample size, N = 148.

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Figure 2-3 Q19: To what extent do you believe that these measures will support achieving the objective of simplifying and accelerating the development of high-quality standards? Sample size=148



Source: Targeted survey to industry organisations and companies - SMEs

Consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for the measures proposed to increase the responsiveness of the ESS under Policy Option 1 .

- The majority of respondents to the targeted survey to NSBs/NCs/NSOs (46 %, 17 out of 37 respondents) indicated that introducing a temporary Presumption of Conformity for standardisation deliverables other than standards would contribute to simplifying and accelerating the development of high-quality standards to a very large extent[274]. To the contrary, only 3 % (1 out 37 respondents) of respondents indicated that this measure would not contribute to achieving the objective[275].

- NSBs/NCs/NSOs were generally not supportive of the use of Common Specifications by the European Commission as fall-back to harmonised standards. Most of respondents to the targeted survey to NSBs/NCs/NSOs (65 %, 24 out of 37) indicated that the measure would not contribute to simplifying and accelerating the development of high-quality standards, and 5 % (2 out of 37 respondents) indicated that the measure would only contribute to the goal to a small extent[276]. Concerning the share of respondents endorsing the measure, 3 % (1 out of 37) indicated "to a very large extent", 5 % (2 out

[274] Targeted survey to NSBs/NCs/NSOs (*Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[275] Targeted survey to NSBs/NCs/NSOs (*Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[276] Targeted survey to NSBs/NCs/NSOs (*Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.

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of 37 respondents) "to a large extent", while 11 % (4 out of 37 respondents) indicated "to a moderate extent"[277].

- Similarly, the results of the to the targeted survey to NSBs/NCs/NSOs reveal overall low support from NSBs for including stronger ESO obligations, monitoring and KPIs, to anticipate and address standardisation needs earlier in the technological lifecycle. The majority (51 %, 19 out of 37 respondents) indicated that this measure would not support the achievement of the objective, and 14 % (5 out of 37 respondents) indicated that the effect would be small[278]. However, some NSBs showed moderate support for this measure, with 22 % (8 out of 37 respondents) indicating that it would contribute to the objective "to a moderate extent" and 14 % (5 out of 37 respondents) indicating "to a large extent"[279]. This is consistent with the results of the Public Consultation, where 72 % (26 out of 37 respondents) of NSBs/NCs/NSOs which responded to the consultation revealed the same scepticism for this measure[280].

- NSBs/NCs/NSOs show positive views on the simplification and digitalisation of the process, even though they are generally more cautious about its impact compared to other measures endorsed. Most respondents (41 %, 15 out of 37 respondents) indicated that the measure would contribute to the objective to a moderate extent[281]. Approximately a third of respondents (32 %, 12 out of 37 respondents) indicated that the contribution would be large, while 24 % (9 out of 37 respondents) indicated that it would be very large[282]. In their responses to the OPC, NSBs/NCs/NSOs showed strong support for the simplification of the standardisation process. The majority of respondents among NSBs/NCs/NSOs (92 %, 33 out of 37) indicated that they strongly agree with the measure[283]. Similarly, 72 % of respondents (26 out of 37 respondents) strongly agreed that the process should be digitalised[284].

Consultations with the ESOs indicate overall support for the measures proposed to increase the responsiveness of the ESS under Policy Option 1.

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[277] Targeted survey to NSBs/NCs/NSOs (*Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*) Sample size, N = 37.
[278] Targeted survey to NSBs/NCs/NSOs (*Q10: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[279] Targeted survey to NSBs/NCs/NSOs (*Q10: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[280] Public consultation - NSBs/NCs/NSOs (*Please share your views on the following approaches to improve speed and flexibility of standardisation processes: Level of agreement*). Sample size, N = 37.
[281] Targeted survey to NSBs/NCs/NSOs (*Q10: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[282] Targeted survey to NSBs/NCs/NSOs. (*Q10: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[283] Public Consultation - NSBs/NCs/NSOs (*Please share your views on the following approaches to improve speed and flexibility of standardisation processes: Level of agreement*). Sample size, N = 37.
[284] Public Consultation - NSBs/NCs/NSOs (*Please share your views on the following approaches to improve speed and flexibility of standardisation processes: Level of agreement*). Sample size, N = 37.

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- In-depth interviews with CEN-CENELEC and the workshop with the HLF sherpa sub-group confirmed that Policy Option 1 could bring benefits by reinforcing ongoing efforts by the ESOs and NSBs to streamline the drafting of Ens, for instance greater digitalisation of processes, earlier quality checks before submission to the Commission, and agreements with other SDOs to integrate their standards into the ESS. ETSI also expressed overall support towards this option although it adopted a more neutral stance towards the revision of the Standardisation Regulation.

Annex III and societal stakeholders also support for the measures proposed to increase the responsiveness of the ESS under Policy Option 1, as it would preserve the integrity of their influence and ensure their continued inclusiveness in the ESS.

PO 2: ESS centred on ESO's with new flexibilities

Industry representatives and companies, including SMEs, expressed mixed views towards the measures proposed to increase the responsiveness of the ESS under Policy Option 2 and would support it only in certain specific cases.

- Industry representatives and companies expressed uncertainty regarding the possibility of opening the system to other SDOs. In the OPC, 61 % of industry representatives and companies (182 out of 320) disagreed that *the Commission should have the option to request the development of new standards by actors beyond the existing European Standardisation Organisations, provided that they work in an inclusive manner with balanced participation of relevant European stakeholders*[285]. This view was also reflected in the targeted survey to industry and companies, in which most respondents considered that revising the list of ESOs in Annex I to the Regulation would have no (32 %, 79 out of 247) or small (17 %, 41 out of 247) impact on speed and responsiveness[286]. Some contributions expressed concern that opening requests to other SDOs might lead to market fragmentation, reduced inclusiveness, and divergent approaches that may be challenging for SMEs to navigate. At the same time, some contributions suggested that, in fast-moving technological sectors, increased flexibility could improve the responsiveness of the system[287].

- In the targeted survey to industry and companies, respondents considered the re-establishment of a EU Chief standardisation officer, with increased resources, to be beneficial for ESS. Most respondents perceived *increased involvement and coordination of EU experts by the European Commission in international standardisation, and promotion of the European Commission as a centre of expertise*, as a moderate (34 %, 83 out of 247) or high (25 %, 61 out of 247) benefit, compared with 16 % (39 out of 247) who viewed it as a cost[288].

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[285] Public Consultation - companies and industry associations (*Q8. Please share your views on the following approaches to improve speed and flexibility of standardisation processes*). Sample size, N=320.
[286] Targeted survey to industry and companies (*Q15: To what extent do you believe that this measure will support achieving the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 247.
[287] Contributions from the Call for Evidence, Public Consultation (position papers) and targeted survey (Free text comments following *Q15: To what extent do you believe that this measure will support achieving the objective of simplifying and accelerating the development of high-quality standards?*).
[288] Targeted survey to industry and companies (*Q51: Please indicate the extent to which the measures listed below impact your organisation*). Sample size, N = 247.

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- Representatives of SMEs were also cautious about involving other SDOs in the system, noting that the current framework plays an important role in ensuring contributions from all Member States and affected stakeholder groups. In the OPC, 44 % of respondents among SMEs (32 out of 72) agreed that the *standardisation framework should be opened to allow other organisations or consortia to respond to specific standardisation requests alongside the recognised ESOs, provided they meet a set of pre-defined criteria, such as inclusiveness, ensuring the quality of their work*. In addition, 44 % of respondents among SMEs (32 out of 72) agreed that *the Commission should have the option to request the development of new standards by actors beyond the existing European Standardisation Organisations, provided that they work in an inclusive manner with balanced participation of relevant European stakeholders*[289], while 37 % (24 out of 72) disagreed. At the same time, in the targeted survey to industry and companies, SME representatives considered the creation of an EU Expert Centre to be beneficial for the ESS. In particular, 59 % (88 out of 148) of respondents perceived *increased involvement and coordination of EU experts by the European Commission in international standardisation, and promotion of the European Commission as a centre of expertise*, as a benefit, compared with 17 % (25 out of 148) who viewed it as a cost[290].

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for the measures proposed to increase the responsiveness of the ESS under Policy Option 2.

- With regards to the possibility of sending Standardisation Requests to other SDOs in pre-defined cases, and the possibility to use and reference standards from other SDOs, the majority of respondents to the targeted survey to NSBs/NCs/NSOs indicated that they do not support the measure (57 %, 21 out of 37 respondents), and 14 % (5 out of 37 respondents) indicated that the measure would contribute to a small extent to achieving the objective[291]. NSBs are also less supportive towards integrating existing standards and technical specifications from other SDOs when ESOs cannot deliver. The majority of respondents to the targeted survey to NSBs/NCs/NSOs indicated that they do not support this measure (57 %, 21 out of 37 respondents), and 14 % (5 out of 37 respondents) indicated that the measure would contribute to a small extent to achieving the objective[292]. Similarly, 58 % (22 out of 37 respondents) of NSBs which responded to the OPC indicated that they strongly disagree with the measure, and 11 % (4 out of 37) indicated that they somewhat disagree[293].

- Concerning the creation of an EU expert Centre, led by a Chief Standardisation Officer to pilot the ESS and lead development of common specifications, most of respondents to the targeted survey to NSBs/NCs/NSOs (65 %, 24 out of 37 respondents) indicated

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[289] Public Consultation – SMEs (*Q8. Please share your views on the following approaches to improve speed and flexibility of standardisation processes*). Sample size, N=72.
[290] Targeted survey to industry and companies – SMEs (*Q51: Please indicate the extent to which the measures listed below impact your organisation*). Sample size, N=148.
[291] Targeted survey to NSBs/NCs/NSOs (*Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[292] Targeted survey to NSBs/NCs/NSOs (*Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[293] Public Consultation - NSBs/NCs/NSOs (*Please share your views on the following approaches to improve speed and flexibility of standardisation processes: Level of agreement*). Sample size, N = 37.

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that the measure would not contribute to simplifying and accelerating the development of high-quality standards, and 5 % (2 out of 37 respondents) indicated that the measure would only contribute to the goal to a small extent[294].

Consultations with the ESOs indicate overall less support for the measures proposed to increase the responsiveness of the ESS under Policy Option 2 than for Policy Option 1.

The main concerns expressed by CEN-CENELEC relate to policy measures involving other SDOs, as they consider that these could create risks and uncertainties regarding users' trust in the standardisation process[295].

Annex III organisations and societal stakeholders support the measures proposed to increase the responsiveness of the ESS under Policy Option 2, provided that existing guarantees of their inclusiveness are maintained, including in cases where other SDOs are involved. One of the concerns expressed in the OPC and in the in-depth interviews with Annex III organisations is that participation in other SDOs might increase their costs as their experts would have to cover other organisations beyond the ESOs.

PO 3: Open ESS managed by the Commission

Industry organisations and companies are generally opposed to the measures proposed to increase the responsiveness of the ESS under Policy Option 3.

- The main concerns were a lower guarantee of consensus-building in the standard development process, and a fragmentation that would overcomplicate the system[296]. These concerns are confirmed by the results of the targeted survey to industry and companies, where most of respondents indicated that open procurement of standards, with no privileges for ESOs, would contribute to simplifying and accelerating the standard development system to no (33 %, 81 out of 247), small (13 %, 33 out of 247), or a moderate (19 %, 46 out of 247) extent[297]. Similarly, in the OPC, 55 % of respondents among companies and business associations (161 out of 291) disagreed about that the *standardisation framework should be opened to allow other organisations or consortia to respond to specific standardisation requests alongside the recognised ESOs, provided they meet a set of pre-defined criteria, such as inclusiveness, ensuring the quality of their work*, while 32 % (92 out of 291) agreed. At the same time, respondents from companies and industry associations replying to the OPC showed broad support for the necessity of a *set of clear criteria that standardisation organisations must meet to be recognised as an ESO*, with 83 % (240 out of 320) agreeing[298].

- SME representatives were uncertain about whether open selection of SDOs for standardisation requests would simplify or accelerate the development of high-quality

[294] Targeted survey to NSBs/NCs/NSOs: Q13: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards? Sample size, N = 37.
[295] Targeted interview with ESOs.
[296] Contributions by the Call for Evidence, Public Consultation and case study interview.
[297] Targeted survey to industry and companies (*Q51: Please indicate the extent to which the measures listed below impact your organisation*). Sample size, N=247.
[298] Public Consultation - companies and industry associations (*Q11. Please share your views on the following approaches related to the role of the European Standardisation Organisation*). Sample size, N=320.

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standards. In the targeted survey to industry and companies, most respondents among SMEs indicated that open procurement of standards, with no privileges for ESOs, would contribute to the objective to no (30 %, 45 out of 148), small (14 %, 20 out of 148), or moderate (21 %, 31 out of 148) extent[299].

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) indicate opposition to the measures proposed to increase the responsiveness of the ESS under Policy Option 3, especially for the open selection of SDOs for Standardisation requests.

- The majority of respondents to the targeted survey to NSBs/NCs/NSOs (65 %, 24 out of 37 respondents) indicated that the measure would not contribute to achieving the goal of simplifying and accelerating the development of standards[300]. This is confirmed by the results of the OPC where most NSBs/NCs/NSOs (78 %, 28 out of 37 respondents) strongly disagreed with the measure[301]. Only 1 National Standardisation Body (3 % of respondents) showed support for the measure[302].

In-depth interviews with CEN-CENELEC confirmed that **the measures proposed to increase the responsiveness of the ESS under Policy Option 3 are strongly opposed by ESOs**, as it would require an overhaul of their financing structure and their ability to deliver hENs.

Annex III and societal stakeholders are also worried about potential negative spillovers of the measures proposed to increase the responsiveness of the ESS under Policy Option 3 on their participation in standardisation. Measures considered to mitigate the risks are considered relevant but not sufficient.

2.2. SO2: ensuring sustainability of the ESS

PO 1: modernised ESO's monopoly

Industry organisations and companies overall support for the measures related to the sustainability of the ESS under Policy Option 1. In particular, SMEs clearly expressed strong support towards the different measures envisaged. More specifically:

- In the targeted survey to industry and companies, most respondents supported the introduction of strong obligations concerning SMEs and societal stakeholders' involvement, including on voting rights to enhance the level of inclusiveness and involvement in the standardisation processes to a large extent (19 %, 47 out of 247 respondents) and to a very large extent (21 %, 52 out of 247 respondents)[303]. In addition, most respondents consider improved support for expert participation is offered and/or the relation between EU Research and Innovation (R&I) funded projects and

[299] Targeted survey to industry and companies – SMEs (*Q51: Please indicate the extent to which the measures listed below impact your organisation*). Sample size, N=148.
[300] Targeted survey to NSBs/NCs/NSOs (*Q16: To what extent do you believe that these measures will support the achievement of the objective of simplifying and accelerating the development of high-quality standards?*). Sample size, N = 37.
[301] Public consultation (*Please share your views on the following approaches related to the role of the European Standardisation Organisation (ESOs): Agreement*). Sample size, N = 37.
[302] Public consultation (*Please share your views on the following approaches related to the role of the European Standardisation Organisation (ESOs): Agreement*). Sample size, N = 37.
[303] Targeted survey to industry and companies (*Q37: To what extent do you think that these measures will support the achievement of the objective to inclusiveness and involvement in the standardisation processes?*). Sample size, N = 247.

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standardisation processes to be beneficial for participation and inclusiveness of the ESS, to a large (24 %, 60 out of 247 respondents) or very large extent (30 % , 74 out of 247 respondents).

- Similar support was expressed for promoting a standardisation ecosystem for innovation and pre-normative work. Most respondents to the targeted survey to industry and companies indicated that the measure would be beneficial to a large (23 %, 57 out of 247 respondents) or very large extent (22 %, 54 out of 247 respondents)[304]. In addition, as outlined in the SME workshop, the time required from expert staff to engage in these processes has emerged as one of main barriers to participating in standardisation activities. This time cost is partly linked to the difficulty of knowing precisely when, during lengthy meetings, topics of direct relevance to specific experts will be discussed. More streamlined organisation of standardisation activities, allowing experts to be involved only in the phases where their contribution is effectively needed, could therefore strengthen incentives for SME participation in the ESS[305]. This could be further supported by making greater use of online participation tools, where appropriate, to facilitate the involvement of SME experts[306]. In the SME workshop, participants also highlighted the importance of encouraging academic participation in standardisation, noting that such involvement is not currently valued sufficiently in academic career assessment. Strengthening the role of standardisation within vocational education and training was also proposed as a way to broaden the future base of experts able to contribute to standardisation activities[307].

- The measure related to the introduction of transparency requirements on participation to standardisation also received positive feedback from companies and industry organisations. In the OPC, most respondents among industry organisations (42 %, 121 out of 291) indicated that they strongly agree that greater transparency is needed regarding the stakeholders involved in technical committees and working groups developing harmonised European standards[308].

- Results of the targeted survey to industry and companies indicate that most SME respondents consider improved support for expert participation and the strengthened link between EU Research and Innovation (R&I) funded projects and standardisation processes as beneficial, to a large (26 %, 38 out of 148 respondents) or very large extent (33 %, 49 out of 148 respondents)[309]. Similar support was expressed for promoting a standardisation ecosystem for innovation and pre-normative work, most SMEs agreeing that this would be beneficial to a large (26 %, 38 out of 148 respondents) or very large

[304] Targeted survey to industry and companies (*Q33: To what extent do you think that these measures will support the achievement of the objective to improve inclusiveness and involvement in the standardisation processes?*). Sample size, N = 247

[305] SME workshop.

[306] Targeted survey to industry and companies – SMEs. Sample size, N = 148.

[307] SME workshop.

[308] Public Consultation – Industry organisations (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 320.

[309] Targeted survey to industry and companies – SMEs (*Q33: To what extent do you think that these measures will support the achievement of the objective to improve inclusiveness and involvement in the standardisation processes?*) Sample size, N = 148.

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extent (22 %, 33 out of 148 respondents)[310]. Moreover, participants to the SME workshop highlighted the importance of encouraging academic participation in standardisation, noting that such involvement is not currently valued sufficiently in academic career assessment.

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for the measures related to the sustainability of the ESS under Policy Option 1. More specifically:

- Interviews with NSBs provided information to assess the impact of accessibility measures on the market of harmonised standards. Using data gathered from the interviews with NSBs, the EU standardisation market was estimated at approximately EUR 500 million annually, with around 61% of revenues originating from other sources, 33 % from the sales of other standardisation deliverables, and 6 % from the sales of harmonised standards. These figures were validated in the NSBs' workshop.

- Interviews with NSBs revealed significant variation in the number of standards downloads across respondents, ranging from 12 000 to 223 000 downloads annually. Downloads of European Standards (ENs) ranged between 4 005 and 148 000, accounting for between 38 % and 95 % of all standards downloads. In comparison, downloads of harmonised European Standards (hENs) ranged from 5 984 to 28 800, representing between 10 % and 48 % of total downloads. The interviews also highlighted differences in pricing practices, with the price of ENs ranging from EUR 36 to EUR 150, while hENs were generally priced between EUR 100 and EUR 120. In addition, respondents indicated that small and medium-sized enterprises (SMEs) represented a substantial share of their customer base, accounting for between 50 % and 99 % of users. These figures were validated in the NSBs' workshop.

- With regard to the impact of readability platforms and open access to standards, the findings of the consultations with NSBs suggest that the effects on revenues and costs have so far been limited and uneven across respondents. Only 3 out of the 17 interviewees reported experiencing a significant change in their revenues, with the average declared loss amounting to approximately 6 % of total revenues. At the same time, 5 out of 17 respondents indicated that they had not observed any significant change, while 4 out of 17 reported no impact at all. Despite these relatively limited immediate effects, all interviewees expressed concern about the potential implications of introducing open access to standards as a general rule, noting that such a development could potentially affect up to 100 % of their revenues.

- Regarding increased incentives for experts' participation in standardisation, most NSBs/NCs/NSOs which responded to the OPC indicated that they strongly agree with the measure (88 %, 30 out of 34 respondents to the question)[311].

- With regard to transparency requirements on participation in standardisation, most NSBs/NCs/NSOs which responded to the OPC (57 %, 20 out of 35 respondents to the

[310] Targeted survey to industry and companies – SMEs (*Q33: To what extent do you think that these measures will support the achievement of the objective to improve inclusiveness and involvement in the standardisation processes?*) Sample size, N = 148.
[311] Public Consultation- NSBs/NCs/NSOs (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 37.

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question) indicated they strongly agree with the measure[312]. In addition, 23 % of respondents (8 out of 35 respondents to the question) indicated that they somewhat agree with the measure, while 11 % (4 out of 35 respondents to the question) indicated that they are neutral[313]. Conversely, 6 % (2 out of 35 respondents to the question) indicated that they somewhat disagree and 3 % (1 out of 35 respondents to the question) indicated that they strongly disagree[314].

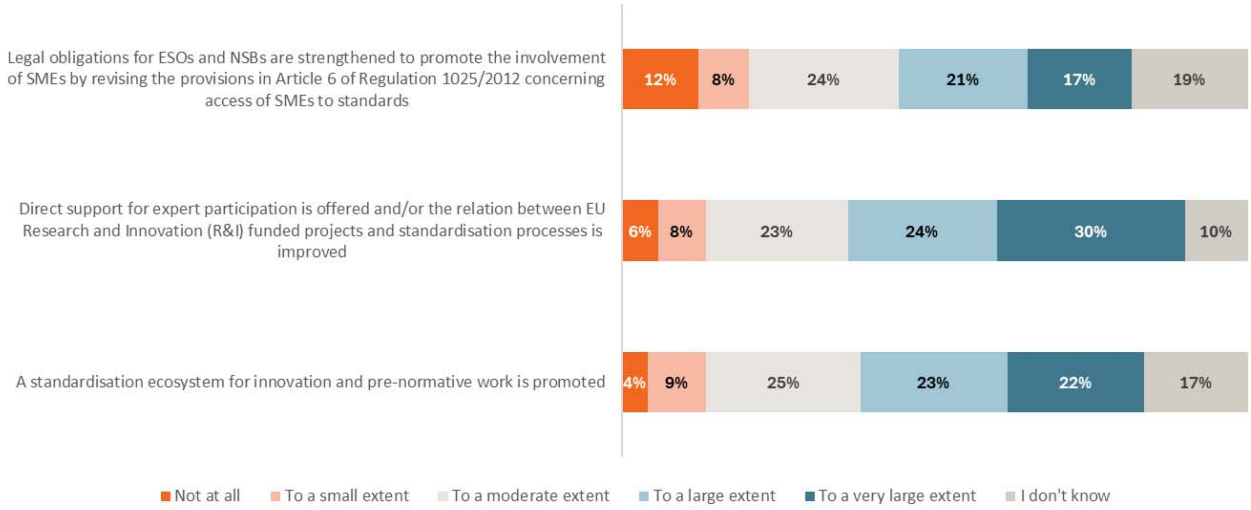
Annex III and societal stakeholders confirm strong support towards the measures envisaged in Policy Option 1 as they could enable a wider inclusion of civil society interests at European and national level.

PO 2: ESS centred on ESO's with new flexibilities

Industry organisations and companies overall support for the measures related to the legal obligations on access to standards under Policy Option 2, although views differ regarding their likely effectiveness and the type of measures considered most impactful.

- Most respondents to the targeted survey to industry and companies (24 %, 60 out of 247) indicated that the measure proposed under Policy Option 2 with regards to access to standards would be beneficial to a moderate extent, 21 % (50 out of 247 respondents) indicated to a "large extent", and 17 % (42 out of 247) a "very large extent"[315].

Figure 2-4 Q33:To what extent do you think that these measures will support the achievement of the objective to improve inclusiveness and involvement in the standardisation processes?, Sample size = 247



Source: Targeted survey to industry organisations and companies

[312] Public Consultation- NSBs/NCs/NSOs (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 37.
[313] Public Consultation- NSBs/NCs/NSOs (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 37.
[314] Public Consultation - NSBs/NCs/NSOs (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 37.
[315] Public Consultation – Industry organisations (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 320.

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Among industry organisations and businesses, evidence from the OPC confirms a broadly positive but more differentiated support of inclusiveness measures under Policy Option 2.

- Strongest support is observed for practical facilitation tools rather than binding governance reforms. For instance, increased capacity building for European experts receives high levels of agreement, with 50 % respondents among industry representatives (146 out of 292) expressing indicating that they strongly agree[316].

- In the OPC, most industry actors and societal stakeholders think that legally relevant content of harmonised standards should be freely accessible. However, some industry contributions to Call for Evidence and OPC expressed the need to compensate the foregone revenues to guarantee the economic sustainability of the ESS. In the OPC, most SMEs strongly agreed that the legally relevant content of standards should be published and freely accessible by default (63 %, 39 out of 62 respondents to the question)[317]. This position is also confirmed in the targeted survey sent to industry and companies, where most respondents among SMEs indicated that the measure would contribute to achieving the objective to a large extent (33 %, 49 out of 148 respondents) and a very large extent (16 %, 23 out of 148 respondents)[318].

- SMEs strongly supported the measures envisaged in Policy option 2 regarding inclusiveness. In the targeted survey, most SME respondents considered that strengthening legal obligations for ESOs and NSBs to promote SME involvement, by revising Article 6 of Regulation (EU) No 1025/2012, would contribute to large (25 %, 37 out of 148 respondents) and very large extent (18 %, 27 out of 148 respondents) to improving inclusiveness and participation in the standardisation process[319].

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for measures related to inclusiveness under Policy Option 2.

- The majority of NSBs/NCs/NSOs showed little support for this binding legal obligations on NSBs for involvement of SMEs/societal stakeholders revising the provisions in Art. 6. Most NSBs/NCs/NSOs which responded to the OPC indicated that they strongly disagree (43 %, 15 out of 35 respondents to the question) and somewhat disagree (43 %, 15 out of 35 respondents to the question) with the measure. Similarly, most NSBs/NCs/NSOs which responded to the survey to NSBs/NCs/NSOs (54 %, 24 out of 37 respondents) indicated that providing free access to legally relevant content would not contribute to achieving the objective. This is confirmed by the results of the

[316] Public Consultation – Industry organisations (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 320.
[317] Public Consultation – SMEs (*Please share your views on the following statements related to potential measures to improve access to standards*). Sample size, N = 72.
[318] Targeted survey to industry and companies – SMEs (*Q45: To what extent do you think that these measures will support the achievement of the objective to improve access to standards and legal quality of the standardisation process?*). Sample size, N = 148.
[319] Targeted survey to industry and companies – SMEs (*Q33: To what extent do you think that these measures will support the achievement of the objective to improve inclusiveness and involvement in the standardisation processes?*). Sample size, N = 148.

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OPC where 63 % of respondents (22 out of 35 respondents to the question) indicated that they strongly disagree with the measure[320].

Annex III organisations and societal stakeholders confirm strong support towards the measure envisaged in Policy Option 2 with regards to inclusiveness as they could enable a wider inclusion of civil society interests also at national level.

PO 3: Open ESS managed by Commission

The additional measures envisaged in Policy option 3 to keep the inclusiveness of SMEs and civil society also in other SDOs were considered necessary by Annex III organisations, to ensure that their societal interest remain balanced in the standardisation process, if the system is fully open. However, Annex III organisations and societal stakeholders expressed concerns whether these measures would be able to mitigate the negative spillovers for participation and influence analysed under SO1 above. Binding obligations built in the current ESS (*cf.* Policy option 2) were considered more effective to increase inclusiveness of SMEs. Annex III organisations also expressed concerns about a possible voting procedure at the current setting. They encouraged exploring measures to promote more constructive engagement among stakeholders, especially civil society, during the consensus-binding process, rather than focusing on voting rights *per se*[321]. Voting procedure may risk of being ineffective due to their relative voting weight in TCs and WGs. However, in the OPC, national societal stakeholders were more in favour of the introducing voting rights for SMEs, consumers and other societal stakeholders (Annex III) in the standardisation process.

Among industry organisations and businesses, there is differentiated support of inclusiveness measures under Policy Option 3.

- Most SME respondents in the targeted survey to industry and companies considered that strong obligations concerning SMEs and societal stakeholders' involvement, including voting rights, would improve inclusiveness and participation in the standardisation process to a moderate (24 %, 36 out of 148 respondents), large (25 %, 37 out of 148 respondents) or very large extent (18 %, 27 out of 148 respondents). By contrast, large enterprises appear more uncertain in their expectations. Among these respondents, the share expressing support falls to 31 % (31 out of 99), while 39 % (39 out of 99) consider that the measure would affect the objective to no extent or only small extent.

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for policy option 3 as regards inclusiveness.

- Most NSBs/NCs/NSOs which responded to the OPC (77 %, 27 out of 35 respondents to the question) indicated that they strongly disagree with introducing requirements on inclusiveness for SDOs to accept Standardisation Requests regarding SMEs and societal stakeholders' involvement, including on voting procedures and 6 % (2 out of 35 respondents to the question) indicated that they somewhat disagree[322]. On the contrary, 11 % (4 out of 35 respondents to the question) indicated that they somewhat agree with

[320] Public consultation – NSBs/NCs/NSOs (*Please share your views on the following statements related to potential measures to improve access to standards*). Sample size, N = 37.
[321] In-depth interviews with all four Annex III organisations.
[322] Public Consultation – NSBs/NCs/NSOs (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 37.

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the measure and 6 % (2 out of 35 respondents to the question) indicated that they strongly agree[323].

- The majority of respondents to the targeted survey to NSBs/NCs/NSOs (54 %, 20 out of 37 respondents) indicated that publishing legally relevant part of harmonised standards in the OJEU would not contribute to achieving the objective of increasing participation and access[324]. Similarly, 11 % (4 out of 37 respondents) indicated that this measure would contribute to achieving the objective to a little extent[325]. On the contrary, 14 % (5 out of 37 respondents) indicated that it would contribute to a moderate extent and 14 % (5 out of 37 respondents) indicated "to a large extent"[326]. Only 1 respondent (3 %) indicated that this measure would contribute to achieving the objective to a very large extent[327].

- Most importantly, interviews with NSBs/NCs/NSOs reveal that there is high concern that the measures related to access to standards under Policy Option 3 may result extremely disproportionate costs for them. NSBs sell services linked to standards, including hENs, in an exclusive way. The range of services could be extremely wide (training, support in compliance, process integration etc.) and interviews with 17 NSBs show that many NSBs are already expanding their portfolio of services. Considering that the share of revenues coming from the selling of standards, including hENs, is a minor one in almost all NSBs it could be assumed that losing their asserted copyrights would have a much higher effect on revenues. This effect is not easy to calculate but could potentially affect the whole business model of many NSBs.

2.3. SO3: Strengthening the EU's position in international standardisation

PO 1: modernised ESO's monopoly

Industry organisations and companies overall support for measures related to strengthening the EU's position in international standardisation under Policy Option 1.

- In the targeted survey to industry organisations and companies, most respondents indicated that an improved an increased involvement and coordination of EU experts by the European Commission in international standardisation would contribute to fostering the EU presence on international standardisation, to a moderate (21 %, 51 out of 247),

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[323] Public Consultation – NSBs/NCs/NSOs (*Please share your views on the following potential measures to improve inclusiveness and stakeholder participation*). Sample size, N = 37.
[324] Targeted survey to NSBs/NCs/NSOs (*Q25: To what extent would you support the following measures to improve access to standards in line with the requests of the Court of Justice of the European Union?*). Sample size, N = 37.
[325] Targeted survey to NSBs/NCs/NSOs (*Q25: To what extent would you support the following measures to improve access to standards in line with the requests of the Court of Justice of the European Union?*). Sample size, N = 37.
[326] Targeted survey to NSBs/NCs/NSOs (*Q25: To what extent would you support the following measures to improve access to standards in line with the requests of the Court of Justice of the European Union?*). Sample size, N = 37.
[327] Targeted survey to NSBs/NCs/NSOs (*Q25: To what extent would you support the following measures to improve access to standards in line with the requests of the Court of Justice of the European Union?*). Sample size, N = 37.

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to a large (27 %, 67 out of 247), or to a very large (25 %, 61 out of 247)[328]. The impact of this measure was also considered as moderately (34 %, 83 out of 247) or highly (25 %, 61 out of 247) beneficial to respondents' organisations[329]. In OPC, the majority of industry organisations and companies also endorsed the introduction of additional measures - such as financial support and capacity building - to improve participation of experts representing SMEs or civil society in international standardisation process. In particular, most of respondents supported as a means to strengthen EU's international presence, to a somewhat (38 %, 112 out of 320) or to strong (38 %, 112 out of 320) level of agreement[330]. Moreover, most of respondents expected that this measure would benefit their organisation, to a moderate (30 %, 76 out of 320), to a high (21 %, 53 out of 320), to a very high (19 %, 48 out of 320) extent[331]. Some contributions from the Call for Evidence and public consultation further confirm this position. Indeed, stronger EU coordination of Member States' positions and expert participation in international standardisation was considered necessary to strengthen Europe's influence, promote shared strategic positions in innovative sectors such as fuel cells, circular economy, cybersecurity and quantum technologies[332].

- SMEs and industry organisations representing SMEs overall agreed on measures under Policy option 1 to increase EU global relevance. In the targeted survey to industry and companies, most of respondents outlined that an increased involvement and coordination of EU experts by the European Commission in international standardisation, and promotion of the European Commission as a centre of expertise would increase EU global relevance, to a moderate (25 %, 37 out of 148), to a very (30 %, 44 out of 148), or to a very large extent (21 %, 31 out of 148)[333]. Moreover, the majority of SMEs involved in the targeted survey to industry and companies evaluated that the *possibility to restrict participation to standardisation activities supporting Standardisation Requests to EU/EEA stakeholders only, for reasons of sovereignty or security* would strengthen the EU presence and its impact in international standardisation, to a moderate (17 %, 25 out of 148), to a large (13 %, 19 out of 148), or to a very large extent (14 %, 21 out of 148)[334].

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for measures related to strengthening the EU's position in international standardisation under Policy Option 1.

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[328] Targeted survey to industry and companies (*Q49: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N=247.
[329] Targeted survey to industry and companies (*Q51: Please indicate the extent to which the measures listed below impact your organisation*). Sample size, N=247.
[330] Public Consultation (*Please indicate your thoughts on the following potential measures to strengthening the EU's role in international and global standard-setting: Level of agreement*). Sample size, N=320.
[331] Public Consultation (*Please indicate your thoughts on the following potential measures to strengthening the EU's role in international and global standard-setting: Expected benefits for me/my organisation*). Sample size, N=320.
[332] Contributions from the Call for Evidence and Public Consultation (position papers).
[333] Targeted survey to industry and companies – SMEs: (*Q49: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*), Sample size, N=148.
[334] Targeted survey to industry and companies – SMEs (*Q49: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*), Sample size, N=148.

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- Most NSBs/NCs/NSOs which responded to the targeted survey indicated that the improved EU coordination of EU Member States' positions and experts' participation in international standardisation organisations would contribute to achieving the objective only to a small extent (43 %, 16 out of 37 respondents)[335]. Additionally, 16 % (6 out of 37 respondents) indicated that the measure would not contribute to the objective at all, while 11 % (4 out of 37 respondents) believed that the measure would contribute to a moderate extent and another 16 % (6 out of 37 respondents) considered that it would contribute to a large extent[336]. In the OPC, most respondents among NSBs (57 %, 20 out of 35 respondents to the question) indicated that they somewhat agree with the measure and 17 % (6 out of 35 respondents to the question) indicated that they strongly agree[337]. With regard to the possibility of restricting participation to standardisation activities supporting Standardisation Requests to EU/EEA stakeholders only, for reasons of sovereignty or security, NSBs/NCs/NSOs which responded to the targeted survey (59 %, 22 out of 37 respondents) indicated that the measure would not contribute to achieving the objective at all[338]. In addition, 11 % of respondents (4 out of 37 respondents) indicated that the measure would only contribute to achieving the objective to a small extent, while 14 % of respondents (5 out of 37 respondents) indicated that the measure would contribute to a moderate extent[339].

ESOs generally supported measures related to strengthening the EU's position in international standardisation under Policy Option 1. During interviews and in the OPC ESOs were in favour of increased coordination at the international level and were not against restricting standardisation activities to EEA actors only, providing that there is a clear rationale and that there is sufficient time given to organise the work[340].

Annex III organisations took a more neutral stance towards measures related to strengthening the EU's position in international standardisation under Policy Option 1, as they recognised the need to strengthen the EU influence and role at international level rather than restricting participation standardisation activities to EU/EEA stakeholders only, but are open to evaluate potential benefits of operating in a EU-restricted setting[341].

PO 2: ESS centred on ESO's with new flexibilities

[335] Targeted survey to NSBs/NCs/NSOs (*Q30: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N = 37.
[336] Targeted survey to NSBs/NCs/NSOs (*Q30: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N = 37.
[337] Public Consultation - NSBs/NCs/NSOs (*Please indicate your thoughts on the following potential measures to strengthening the EU's role in international and global standard-setting: Level of agreement*). Sample size, N = 37.
[338] Targeted survey to NSBs/NCs/NSOs (*Q30: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*) Sample size, N = 37.
[339] Targeted survey to NSBs/NCs/NSOs (*Q30: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*) Sample size, N = 37.
[340] Interviews with ESOs.
[341] Interviews with Annex III organisations.

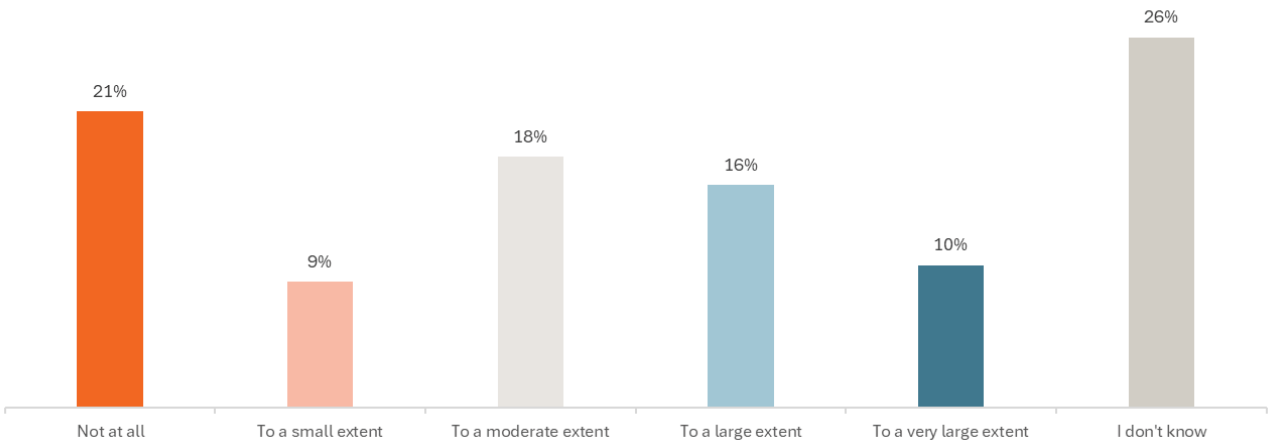
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Industry organisations and businesses showed differentiated support towards measures related to strengthening the international influence of the ESS under Policy Option 2.

- In the targeted survey to industry and companies, respondents did not express a uniform view on the *possibility to derogate from the Vienna and Frankfurt agreements*, as well as to *the 'international first' principle when European strategic and competitive needs are not regarded or potentially damaged by international standardisation activities* and its impact on the EU's international presence. In particular, 21 % of respondents (52 out of 247) assessed that this measure would lead to no impact, 9 % (22 out of 247) to a small impact, 18 % to moderate impact (44 out of 247), 16 % to a large impact (39 out of 148), 10 % to a very large extent (24 out of 247), while 26 % of respondents did not express any assessment on the measure's effects (65 out of 247)[342]. Further details are provided in figure below.

Moreover, it was highlighted that derogation from the Vienna and Frankfurt agreement might damage European industries by hampering global market access and cost control[343].

Figure 2-5 Distribution of answers to Q53 on derogation from the 'international first' principle of the targeted survey to industry and companies, Simple size=247[344]



Source: Targeted survey to industry organisations and companies

- SMEs shared similar views about the impact of the measures related to strengthening the international influence of the ESS under Policy Option 2. In the targeted survey to industry and companies, *the possibility to derogate from the Vienna and Frankfurt agreements, as well as to the principle 'international first' when European strategic and competitive needs are not regarded or potentially damaged by international standardisation activities* was expected to lead to no impact for 18 % of respondents (26 out of 148), to small impact for 9 % (13 out of 148), to a moderate impact for 20 % (29 out of 148), to a large impact for 14 % (20 out of 148), to a very large impact for

[342] Targeted survey to industry and companies (*Q53:To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N=247.
[343] Contributions to the Call for Evidence and public consultation sorted by companies and industry associations.
[344] Targeted survey to industry and companies (*Q53: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*).

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9 % (14 out of 148), while 31 % of respondents could not provide any evaluations (46 out of 148)[345].

The consultations with National Standardisation Bodies (NSBs/NCs/NSOs) reveal varying levels of support for the measures related to strengthening the international influence of the ESS under Policy Option 2.

- The majority of NSBs/NCs/NSOs which responded to the targeted survey (65 %, 24 out of 37 respondents) indicated that the possibility to derogate from the 'international first' principle when ESOs agreement with international standardisation organisations challenge European strategic and sovereignty interests would not contribute to achieving the objective[346]. Only 11 % of respondents (4 out of 37 respondents) indicated that it would contribute to a large extent and 5 % (2 out of 37 respondents) believed that it would contribute to a very large extent[347].

As emerged in the workshop, CEN-CENELEC and NSBs/NCs strongly support the Vienna and Frankfurt agreements and suggest that the possibility to derogate from them should be limited to very specific cases and duly prioritised in a forum-set up like the HLF. However, according to them this measure can already be applied using the current Vienna and Frankfurt agreements[348].

PO 3: Open ESS managed by Commission

Industry organisations and businesses showed little support towards measures related to strengthening the international influence of the ESS under Policy Option 3. Regarding the *End of the automatic 'international first' principle*, industry organisations, including SMEs, are uncertain about the impact of this measure. On the one hand, it could support the development of standards that are more closely aligned with EU interests and values. On the other hand, it may increase the risk of isolating the European standardisation system from international standardisation processes, potentially leading to decoupling and a reduction in European competitiveness[349].

ESOs were opposed to measures related to strengthening the international influence of the ESS under Policy Option 3. ESOs highlighted that moving away from the 'international first' principle could lead to duplication of work, fragmentation, and weaker European participation in international standardisation. This, in turn, may diminish the EU's ability to shape international standards and negatively affect competitiveness and market access for European industry[350].

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[345] Targeted survey to industry and companies – SMEs (*Q53:To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N=148.
[346] Targeted survey to NSBs/NCs/NSOs (*Q32: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N = 37.
[347] Targeted survey to NSBs/NCs/NSOs (*Q32: To what extent do you think that these measures will support the achievement of the objective to strengthen EU presence and impact on international standardisation?*). Sample size, N = 37.
[348] Online workshop with NSBs/NCs/NSOs.
[349] Analysis of written contributions to the Call for Evidence and public consultation, as well as in-depth interviews, shows that this is the major feedback from industry associations, ESOs and NSBs.
[350] Online workshop with NSBs/NCs/NSOs.

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Annex III organisations also raised proportionality concerns, noting that the measure could isolate EU stakeholders if not carefully implemented[351].

[351] Interviews with Annex III organisations.

ANNEX 3: WHO IS AFFECTED AND HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The preferred policy option would have practical implications for businesses, ESOs and NSBs as well as for societal stakeholders. It will contribute to increase the EU's competitiveness, notably in key strategic technologies, and will improve the functioning of the internal market by facilitating the implementation of sectoral legislation relying on the Standardisation Regulation. This would in turn impact EU consumers indirectly, as they would be able to benefit from a high level of protection of public interest, as hENs are turning essential requirements supporting this high-level of protection into operational guidelines for businesses. Citizens would also be able to access and consult the hENs for free, improving the transparency and understanding on EU product and service legislation.

Implications on businesses

The initiative will bring important benefits to businesses. Businesses using hENs to access the internal market will be able to rely on more standards available faster and timelier, leading to important savings in conformity assessments costs. Businesses will also benefit from a more influential ESS in international standardisation organisations through increased opportunities and competitiveness in international trade. Businesses will benefit from free access to hENs, leading to savings on their purchase of standards. Last, businesses that wish to take part to the standardisation process will benefit from targeted improvements that will facilitate their participation by decreasing the costs of participation. SMEs will benefit from the initiative, as the different costs and benefits linked to standardisation (conformity assessment costs, costs of purchasing hENs and costs of participating in standardisation) generally represent a higher share of their costs than for large undertakings.

Implications on ESOs and NSBs

The initiative will have important implications for ESOs and NSBs and will require them to undertake changes in the way they operate. ESOs and NSBs will have to compensate the foregone sales of hENs stemming from the free access to hENs, for example by identifying new sources of revenues linked to the move to a digital-centric approach to standardisation. This may in particular create difficulties for some NSBs currently heavily relying on such sales to finance their activity. ESOs and NSBs will also incur additional costs linked to more stringent obligations to foster participation of SMEs and civil society and to set up transparency register to identify the interests represented in the standardisation process. ESOs and NSBs will indirectly benefit from the initiative as a more responsive ESS would increase the incentives of EU businesses to take part to the standardisation process and to develop new standards.

Implications on societal stakeholders and civil society taking part in standardisation activities

Organisations representing societal stakeholders and civil society will benefit from the initiative through improved access and influence in the standardisation process at national level. Some additional costs might arise for them to ensure their participation in other SDOs providing hENs to the Commission. Positive spillovers are also expected for researchers, as their participation will be incentivised. They will also benefit from the free and unrestricted access to hENs.

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2. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount (1)***	***Comments***
Direct benefits		
Compliance cost savings	EUR 295 million; Businesses are the recipient of the benefits. They are the result of a reduced need for conformity assessments due to faster availability of hENs.	Businesses SMEs
hENs costs savings	EUR 30 million; Companies are the main recipient of the benefits. These benefits represent decreased costs to purchase hENs as hENs become available for free. The measures also benefit all the users of hENs (civil society organisations, research community).	Businesses Civil society organisations and research community Citizens
Inclusiveness costs savings	EUR 1.9 million; SMEs, societal stakeholders and researchers are the main recipients from NSBs' measures to increase inclusiveness.	SMEs Civil society organisations
Indirect benefits		
Competitiveness in the Single Market	Not quantifiable; increase in responsiveness of the ESS will foster timely availability of hENs and improve the functioning of the internal market, creating efficiencies for companies and facilitating trade in and outside the EU. hENs will also be closer to the state of the art and facilitate innovation diffusion and competitiveness in strategic technologies.	
Increased EU strategic autonomy	Not quantifiable; consolidating EU influence in international standardisation will ensure EU's strategic interests are better reflected in international standards. Increased flexibility to conduct standardisation activities in EU-restricted setting will improve ability of the EU to implement strategic autonomy objectives for strategic technologies.	

(1) Estimates are gross values relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together)

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II. Overview of Costs – Preferred Option (EUR million)									
		Businesses		**ESO/NSBs**		**Annex III Organisations**		**Commission**	
		One-off	**Recur-rent**	**One-off**	**Recur-rent**	**One-off**	**Recur-rent**	**One-off**	**Recur-rent**
Measure 1.1 (integration of other SDOs spec. by ESOs)	Direct adjustment costs			**Limited costs** of cooperation agreements with alternative SDOs					
	Administra-tive costs								**0.194** (1 FTE)
Measure 1.2 (CS)	No additional costs								
Measure 1.3 (Tempo-rary PoC)	Direct adjustment costs		**Limited costs** in case of mis-alignment with final hEN						
Measure 1.4 (strategic planning)	Direct adjustment costs		**Very low** (additional participation to HLF)		**Very low** (additional participatio n to HLF)		**Very low** (additional participati on to HLF)		
	Administra-tive costs								**0.194** (1 FTE)
Measure 1.5 (simplificat ion)	Administra-tive costs								**- 0.097** (-0.5 FTE)
Measure 1.7 (experts' participa-tion)	Direct adjustment costs				**Very low** (access of draft standards to researchers)				
Measure 1.8 (Trans-parency registers)	Administra-tive costs			**0.4** (set-up of transparen-cy registers)	**0.6** (mainte-nance of transparen-cy register)				
Measure 1.9 (interna-tional coordi-nation)	Direct adjustment costs		**Very low** (additional participation to HLF)		**Very low** (additional participatio n to HLF)				
	Administra-tive costs								**0.194** (1 FTE)

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Measure 2.1 (alternative SDOs flexibility)	Indirect adjustment costs		**4.5** Additional costs linked to potential duplication of standardi-sation efforts						
	Administra-tive costs								**0.582** (3 FTEs)
Measure 2.2 (Expert Centre)	Administra-tive costs								**0.194** (1 FTE)
Measure 2.3 (un-restricted free access to hENs through registry)	Direct adjustment costs				**Low costs** to set up registry based on existing readibility platforms				
	Opportu-nity costs		**6** (decrease in action grants supporting partici-pation)		**30** (loss of revenues from sales of hENs)				
Measure 2.4 (binding in-clusiveness measures on NSBs)	Direct adjustment costs			**1.9** (binding measures on access of SMEs/civil society)					
Measure 2.5 (targeted derogation to Interna-tional First Principle)	Indirect costs		**Important costs** in sectors where applied to ensure compliance with both hEN and international standard						
	Administra-tive costs								0.194 (1 FTE)

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III. Contribution to the administrative burden reduction targets – Preferred option					
Administrative costs **[M€]**	**New recurrent costs (INs)** (nominal values per year)	**Removed recurrent costs (OUTs)** (nominal values per year)	**Net cost (INs – OUTs)** (nominal values per year)	**New one-off costs (INs)** (annualised total net present value over the relevant period)	**Removed one-off costs (OUTs)** (annualised total net present value over the relevant period)
All businesses		**EUR 295 million** (savings in compliance costs and purchase of hEN)	**EUR 295 million** (savings in compliance costs and purchase of hEN)		
• in which SMEs		EUR 253 million	EUR 253 million		
ESOs and NSBs	**EUR 0.6 million** (maintenance costs of transparency register)		**EUR 0.6 million** (maintenance costs of transparency register)	**EUR 0.04 million** (set up costs of transparency register)	
Public administrations (European Commission)	**EUR 1.6 million**	**EUR 0.1 million**	**EUR 1.5 million**		
Citizens	n.a	n.a	n.a	n.a	n.a

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3. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

IV. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	Expected progress towards the Goal	Comments
SDG no. 3 – Good health and wellbeing	Moderate positive contribution	Faster development and citation of harmonised standards will facilitate quicker implementation of health, safety and consumer protection requirements under Union legislation. Improved access to harmonised standards will also support compliance and safer products and services across the internal market.
SDG no. 9 – Industry, innovation and infrastructure	Significant positive contribution	The preferred option is expected to strengthen the responsiveness and effectiveness of the European Standardisation System, supporting innovation, industrial competitiveness and technological uptake. Faster delivery of harmonised standards, increased flexibility to reference external standards, and the creation of an EU Expert Centre will improve the EU's capacity to support emerging technologies and strategic industrial priorities.
SDG no. 13 – Climate action	Moderate positive contribution	More responsive standardisation processes are expected to facilitate faster implementation of environmental and climate-related legislation. Improved alignment between standards and EU policy objectives may support the uptake of cleaner technologies and sustainable production practices.
SDG no. 8 – Decent work and economic growth	Moderate positive contribution	The preferred option is expected to generate substantial economic benefits through reduced compliance costs, faster market access and lower conformity assessment needs. Estimated savings for businesses amount to up to EUR 295 million, with additional benefits from free access to harmonised standards. Increased SME participation and easier access to standards are also expected to support inclusive economic growth and competitiveness.

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ANNEX 4: ANALYTICAL METHODS

1. METHODOLOGY

The methodology was designed by Intellera's Study Team for DG GROW. In the Inception phase, the Study team liaised with the Commission to finalise the methodology and set up the data collection strategy for both secondary data and primary data collection.

As a first task, the Team defined the problems to be addressed and objectives to be pursued through the revision via a mix of secondary data review and policy interviews with relevant DGs and experts.

Subsequently, the Study team and DG GROW detailed the policy options and underlying measures intended to address the problems and pursue the objectives defined. Based on the options and measures, the Study team identified relevant impact areas, including costs and benefits, drafted the causal chain analysis, and, consequently, prepared the data collection tools: an extraction table for secondary data sources, questionnaires for surveys and interviews and a selection of sectors for the case studies. These outputs were presented in the Interim Report and discussed during several meetings with DG GROW and the Inter-Service Steering Group.

Several data collection activities were carried out:

- **an extensive policy and data review was conducted** (see Annex 16 for the long list of data sources), which included literature, grey literature, official reports and data, as well as about 300 position papers or documents shared by stakeholders during consultations or directly via email.
- **different consultations targeted at different stakeholder groups** (more details in Annex 2, Synopsis Report), including:
    - **one public consultation** open to all EU citizens and organisations.
    - **one targeted online survey for industry organisations and companies**, including SMEs, to gather specific feedback on costs and benefits to be expected from the different options.
    - **one online workshop with the HLF sherpa sub-group,** to discuss policy options and their potential implications with Member States representatives and ESOs.
    - **one online workshop with NSBs/NCs/NSOs,** followed by a **targeted online survey for NSBs/NCs/NSOs**, to gather specific feedback on costs and benefits to be expected from the different options.
    - **In-depth interviews with 17 NSBs/NCs/NSOs**, to gather quantitative details on the potential impact of policy options on revenues, costs, and business models.
    - **In-depth interviews with CEN-CENELEC** and **5 EU industry organisations** to fine-tune quantitative analysis of impacts expected for ESOs, NSBs/NCs/NSOs and companies.
    - **In-depth interviews with all 4 Annex III organisations** to assess the impact of policy options on the representation of societal interests and SMEs in European and international standardisation.
    - **In-depth interviews with relevant DGs of the European Commission** to gather a sectoral-specific assessment.

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The data collection was complemented with 5 sectoral case studies, based on desk research, results of the surveys and additional interviews conducted. The following sectors were analysed: artificial intelligence, electric vehicles, critical space technologies, additive manufacturing and construction.

The estimation of costs and benefits for affected stakeholders, as well as wider impacts, was carried out through a mix of techniques, including the standard cost model, cost-effectiveness analysis, and statistical analysis/regressions.

In addition, several validation exercises were carried out:

- One workshop with SMEs and their EU representative organisations, to validate the analysis considering the specific costs and benefits on SMEs.
- One workshop with HLF sherpa sub-group, to validate the analysis considering the feedback of Members States and ESOs.
- One workshop with NSBs/NCs/NSOs, to validate the analysis considering the specific costs and benefits for NSBs/NCs/NSOs.

These activities informed the comparison among policy options and supported the Commission in the selection of the preferred option. In addition, once the preferred option had been selected, a framework for monitoring and evaluating implementation was elaborated.

2. ANALYTICAL TECHNIQUES AND MODELS

This section presents a detailed description of the data underpinning the calculations, and an explanation of the methods and assumptions that were used to calculate costs and benefits in section 6.

Benefits for businesses generated by faster delivery of hENs

In section 6.2, we estimate the possible average annual savings in each policy option for companies in compliance cost due to the availability of hENs – expected to be the main quantitative impact of the responsiveness objective. The results vary according to policy option:

- Policy option 1: EUR 264 670 557
- Policy option 2: EUR 294 707 183
- Policy option 3: EUR 348 276 852

The following calculations were used:

$$\text{Annual cost savings} = \sum (Q \times P \times F / Y)$$

where

Q = number of companies affected in each sector affected by harmonised legislation

P = cost of undertaking a conformity assessment procedure when hENs are not available

F = Number of conformity assessment "saved" thanks to hENs available in less time compared to baseline

Y = Time period in which cost savings could be experienced

Key sources:

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- Q is taken from Eurostat Enterprise statistics by size class and NACE Rev. 2 activity (from 2021 onwards) [sbs_sc_ovw__custom_21308624]; each legislation linked to present and future hENs was linked to a specific sector. The affected sectors is reported in Annex 5, competitiveness check.
- P is taken from the Evaluation Study, which estimate the savings at EUR 3 700 per hEN used in conformity assessment. It is acknowledged that some sectors declared higher costs, but in the absence of systematic sectoral evidence, we rely on this conservative estimate in all sectors.
- F is the number of conformity assessments one company could save thanks to hENs' presumption of conformity in each sector; the major effect of POs is a reduction of time to make hENs available and therefore an increase in conformity assessment potentially "saved" thanks to more hENs available. This relationship is considered not linear, by using a complexity factor, leading to an expected share of conformity assessment "saved" of 4.7 % in Option 1, 4.8 % in Option 2, 6 % in option 3.
- Y equals 10 years

Key assumptions and limitations

- Q:
    - it is assumed that immediate direct benefits (cost savings) could be expected for 7 % of the total enterprises. This derived from the fact that the annual number of single downloads of hENs in 34 NSBs is 584 800, which represents around the 7 % of the total number of enterprises. This is certainly an underestimation of the potential direct and indirect users of hENs. Most importantly, because many NSBs are adopting a subscription-based model, which give access to a bundle of standards and, therefore, make the relationship between single downloads and individual users difficult to estimate. While this conservative estimate was needed to have a safer and robust figure of direct costs savings, it should be expected that potentially affected enterprises will be much higher in the medium – long term.
- F:
    - it is assumed that two hENs on average are needed per conformity assessment. This in practice depends heavily on each sector and product.
    - It is assumed that for each sector currently covered by hENs, but with no future hEN foreseen in the next 10 years, 1 hEN will be delivered in the next 10 years.

This method based on sectoral data underwent robustness checks based on aggregated data on hENs derived from interviews with NSBs and some assumptions. The following calculations were used:

$$\text{Annual cost savings} = (Q \times P \times F \times S \times \alpha)/ Y$$

Where:

Q = number of average number of companies downloading hENs in one NSB in one year

P = cost of undertaking a conformity assessment procedure when hENs are not available

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F = usage rate of additional hENs more timely available thanks to reduced duration of the standardisation process

S = number of hENs which will be delivered faster thanks to expected time reduction in POs.

α = complexity factor as computed in section 6.5.1

Y = Time period in which cost savings could be experienced

Key sources:

- Q is taken the 17 interviews with NSBs where the average number of hENs downloads per year is estimated to be 17 200. This number is multiplied by 34 NSBs and NCs officially members of CEN-CENELEC.
- P is taken from the Evaluation Study, at EUR 3 700 per product. It is acknowledged that some sectors declared higher costs, but in the absence of systematic sectoral evidence, we rely on this conservative estimate in all sectors.
- F is the extent to which each new hENs timelier available (thanks to the effect of POs) could generate savings through presumption of conformity or less complex conformity assessments, as we cannot expect that all additional hENs will be used by all companies at the same time
- S is the number of hENs which will be delivered faster thanks to time reductions expected in the POs. The relationship is considered not linear and we applied the same complexity factor leading to an expected share of more timely available hENs of 4.7 % in Option 1, 4.8 % in Option 2, 6 % in option 3.
- Y is 10 to ensure consistency with the sector-based approach above.

Key assumptions and limitations

- Q:
    - It is assumed that 1 download equals to 1 company to have an overall aggregation of companies affected
    - The average (17 200) is multiplied by 34 NSBs / NCs in CEN-CENELEC (584 800)
- F:
    - We assume it equals Q divided by the total number of companies affected in the sectors covered by currently available of requested hENs, taken from Eurostat Enterprise statistics by size class and NACE Rev. 2 activity (from 2021 onwards) [sbs_sc_ovw__custom_21308624], i.e. 7%
- S is the ratio of additional hENs on the average number of hENs delivered in the last 7 years (2019-2025), i.e. 232 hENs

The overall results of the sector-based approach and the robustness check are reported below.

Table 4.1 Overall amount of annual costs savings for businesses using hENs, by policy option

Policy Option	Sector based approach
1	EUR 264 670 557
2	EUR 294 707 183

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3	EUR 348 276 852

The savings by policy option are calculated based on the savings generated by each different path from the Commission to obtain harmonised standards:

- hENs obtained from ESOs, including the effects of Measure 1.4 (strategic planning) and Measure 1.5 (simplification).
- hENs obtained from ESOs using one of the new flexibilities introduced in Option 1, either through Measure 1.1 (integration of existing specifications from an alternative SDOs) or through Measure 1.2 (standardisation deliverable providing presumption of conformity).
- hENs directly obtained from alternative SDOs through Measure 2.1: in this case, the average duration time is also reduced by the application of Measure 1.4, but only partly by the application of Measure 1.5, as some of the gains introduced by the simplification of the process with ESOs cannot be applied to standards from alternative SDOs (the gains from not validating the standardisation request from the comitology procedure).

The savings calculated for each different path thus differ from the savings calculated for each policy measure, i.e. when only the effect of the policy measure on the average standardisation delivery time is retained. The table 4.2 below provides the details of the calculation and reconciles the gain from each policy measure with the gains from each standardisation path. The latter presentation of savings is retained in table 1 of section 6 as it more accurately reflects the operational implementation of the standardisation requests.

Table 4.2: Breakdown of savings for businesses by policy measure and by standardisation path used[352]

Total savings for businesses compared to the Baseline by measure and by standardisation path	Measure 1.1	Measure 1.3	Measure 1.4	Measure 1.5	Measure 2.1	Financial savings by standard path	Share of use of hEN path
Policy option 1							
Standards obtained from ESOs through measures 1.1	24		11	11		45	10%
Standards obtained from ESOs through measure 1.3		24	11	11		45	10%
Other standards obtained from ESOs			87	87		174	80%
Total savings by policy measure Policy Option 1	**24**	**24**	**109**	**109**		**265**	**100%**
Policy option 2							
Standards obtained from ESOs through measure 1.1	**24**		**11**	**11**		45	**10%**
Standards obtained from ESOs through measure 1.3		**24**	**11**	**11**		45	**10%**
Other standards obtained from ESOs			**76**	**76**		152	**70%**
Standards obtained from alternate SDOs through measure 2.1			**11**	**4**	**37**	52	**10%**
Total saving by policy measure Policy Option 2	**24**	**24**	**109**	**102**	**37**	**295**	**100%**
Policy option 3							
Standards obtained through ESOs (based on PO1)	**16**	**16**	**73**	**73**		**177**	**67%**
Standards obtained through other SDOs (based on 2.1)			**36**	**14**	**121**	**171**	**33%**
Total savings by policy measure Policy Option 3	**16**	**16**	**109**	**87**	**121**	**348**	**100%**

* Standards from all paths benefit from the effects of policy measures 1.4 and 1.5 that apply horizontally to all hENs; the effect of the simplification measure 1.5 are lower in Policy Option 2 and Policy Option 3 as standards from alternative SDOs do not benefit from the time saved through end of Comitology procedure

Costs for NSBs/NCs/NSOs to apply Art. 6

Data on the costs associated with implementing Article 6 activities were collected through targeted interviews and a survey conducted with National Standardisation Bodies (NSBs). This is equal to EUR 1.2 million for policy measure 1.6 and EUR 1.9 million for policy measure 2.3.

The total additional costs associated with the implementation of Article 6 activities were estimated using the following approach.

[352] Totals may not add up due to rounding.

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$$TC = \sum_{i=1}^{n} (AC_i \times NSB_i \times E)$$

Where:

TC= Total estimated additional costs

AC_i= Average cost of implementing activity i, calculated from targeted interviews and survey responses

NSB_i= Number of National Standardisation Bodies not currently implementing activity i

E= Elasticity factor applied to reflect the expected degree of implementation

n= Number of Article 6 activities considered

For Measure 1.6 specifically, the elasticity factor was set at 0.5

Key Sources

- AC_i= Average cost of implementing activity i, calculated from targeted interviews and survey responses. This data comes from a total of 10 NSBs.
- NSB_i= Number of National Standardisation Bodies not currently implementing activity i. This is equal to 8. This has been calculated by subtrascting the total number of NSBs by the number of NSBs reporting Article 6 activities.
- n= Number of Article 6 activities considered. This is equivalent to:
    - Identify standardisation projects relevant for SMEs
    - Access to standardisation activities without obliging SMEs to become a member of a NSB
    - Abstracts of standards available free of charge on their website
    - Special rates for the provision of standards or providing bundles of standards at a reduced price
    - Other activities

Key assumptions and limitations

- For Measure 1.6, an elasticity factor of 0.5 was applied, reflecting the fact that the strengthened obligation to extend Article 6 activities to civil society organisations would not be legally binding and would therefore likely only be partially implemented in practice.

Costs – benefits analysis

As the policy options entail important transfers in terms of costs between the different actors of the ESS, the table below detail the calculation behind the main costs and benefits assessment in Section 7.2. They highlight the difference between transfers of costs across stakeholders (for instance, the free access to hENs is a cost for ESOs and NSBs but a benefit for users of hENs, mostly businesses) and net costs or benefits that are stemming from each policy option.

The key assumptions are:

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- Free access to standards benefits entirely businesses; while in practice, Annex III and civil society organisations will also benefit from free access to hENs, we assume that the totality of the transfer concern businesses.
- Measures to support SMEs and civil society organisations (measure 1.6 and measure 2.4) incur costs for NSBs (see above) that entirely benefit Annex 3 and civil society organisations, while in reality businesses (SMEs) would also benefit from measure 2.4.
- The EU budget to finance standardisation is assumed to be stable in the next MFF. Measure that requires a compensation from the Commission are considered to be financed through a decrease in the part of the budget that offers most flexibility: the action grants to finance experts' participation in standardisation for priority standardisation requests. This budget amounts to EUR 10 million per year. Increased support from the Commission to a stakeholder group (for instance NSBs) is thus considered to be financed through a decrease in the action grant budget. This is assumed to directly affect businesses, that are generally the ultimate beneficiaries of such grants.
- In policy option 3, the necessary financial support from the Commission to ensure the sustainability of the ESS is higher than the available action grant budget. The impact is thus considered as a "net cost" for the Commission, as it cannot be financed through internal transfer.

The tables 4.3 below express the impact for each stakeholder by line, including transfers from other stakeholders of the ESS in column. A positive figure indicates a benefit while a negative figure indicates a cost. The "Total benefits" and "Total costs" columns sum up the respective costs and benefits incurred by each stakeholder and are the figure capture in Table 3 Costs and benefits of each policy option Section 7.

In policy option 3, the costs incurred by the Commission can be decomposed along the following: EUR 2.7 million linked to the set-up of the EU Standardisation Office (15 FTEs), EUR 5 million necessary to finance ESOs/NSBs on top of the EUR 10 million action grant available in the current budget, and EUR 0.4 to finance Annex 3 organisations' participation in alternative SDOs, also on top of the available action grant budget.

Table 4.3: Details of transfer of costs by policy option

Policy option 1

EUR million	Industry & companies	ESOs and NSBs	Annex III and civil society org.	European Commission	Benefits not linked to transfers	Costs not linked to transfers	Total benefits per stakeholder	Total Costs per stakeholders	Net effect per stakeholder
Industry & companies					265		265	0	265.0
ESOs and NSBs			-1.2			-1.0	0	-2.2	-2.2
Annex III and civil society organisations		1.2					1.2	0	1.2
European Commission						-0.5	0	-0.5	-0.5

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Policy option 2

EUR million	Industry & companies	ESOs and NSBs	Annex III and civil society org.	European Commission	Benefits not linked to transfers	Costs not linked to transfers	Total benefits per stakeholder	Total Costs per stakeholders	Net effect per stakeholder
Industry & companies		30		-6	295	-4.5	325	-10.5	314.5
ESOs and NSBs	-30		-1.9	6		-1.0	6	-32.9	-26.9
Annex III and civil society organisations		1.9					1.9	0	1.9
European Commission	6	-6				-1.5	6	-7.5	-1.5

Policy option 3

EUR million	Industry & companies	ESOs and NSBs	Annex III and civil society org.	European Commission	Benefits not linked to transfers	Costs not linked to transfers	Total benefits per stakeholder	Total Costs per stakeholders	Net effect per stakeholder
Industry & companies		30		-10	348	-15	378	-25	353.0
ESOs and NSBs	-30		0	10		-19.0	10	-49	-39.0
Annex III and civil society organisations				0.4			0.4	0	0.4
European Commission	10	-10				-8.1	10	-18.1	-8.1

3. ESTIMATION OF WIDER IMPACTS

Section 6.7 reports on the macro-economic impacts of policy options. The assessment presented is based on econometric modelling rooted in the literature and a set of assumptions which are presented here below.

Available evidence on the macro-economic impacts of standards

Standards have many roles. They contribute to distribution of technical knowledge, interoperability, a reduced variety of intermediate, but also final goods and quality assurance. These are the main roles of traditional or non-harmonised standards, which tend to be created by industry and other stakeholders in a market-driven approach, but also benefiting of input from research[353].

Harmonised European Standards (hENs), however, are created based on a request from the European Commission and are usually intended to support European regulations. The effects of hENs, therefore, differ from that of other standards. As underlined by previous studies, regulations are generated by more of a top-down approach than standards are (see e.g. Blind et al., 2017[354]; Blind and Münch, 2024[355]). The hENs which support the regulations are less top-down than the regulations, but more so than the non-harmonised standards. The hENs, therefore, constitute a more driven approach than pure regulation without hENs.

[353] Blind, K., Kromer, L., Neuhaeusler, P., Rosenberg, D., Schubert, T. (2024): European Standardisation Panel Survey, European Commission, Blind, K., Kromer, L. The role of research and other inputs for the development and impacts of standards. Journal Technology Transfer (2025). https://doi.org/10.1007/s10961-025-10286-8.

[354] Blind, K., Petersen, S. S., Riillo, C. A. F. (2017): The impact of standards and regulation on innovation in uncertain markets, Research Policy,
Volume 46, Issue 1, 249-264, https://doi.org/10.1016/j.respol.2016.11.003.

[355] Blind, K., Münch, F. (2024): The interplay between innovation, standards and regulation in a globalising economy, Journal of Cleaner Production, Volume 445, 141202, https://doi.org/10.1016/j.jclepro.2024.141202.

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To estimate the stock of harmonised standards per year, the study of the European Commission (2022)[356] has used the EUR-Lex database as a reference to identify all communications of the European Commission referring to hENs and extracted all hENs that were mentioned in these. Then these hENs were matched with the standards released by CEN-CENELEC and ETSI to create a stock of hENs per year. The standards are not always referred to in precisely the same way in EUR-Lex and by CEN-CENELEC-ETSI, so some hENs may be unmatched. Therefore, the applied methodology may miss around 10 % of hENs.

The relative growth in the number of hENs was slightly higher than the relative growth of the remaining ENs from 1997 to 2005. The share of ENs which were harmonised therefore grew in this period. From 2011 through 2017, the number of hENs stagnated, while the number of ENs has grown. Therefore, the share of ENs decreased. On average, approximately 15% of ENs are hENs. Among the sectors with the most hENs are "Manufacturing of Electrical equipment", "Machinery", and "Electricity, gas, steam and air conditioning supply", while "Coke and petroleum" and "IT and information services" have the fewest.

In order to estimate the effects of hENs on productivity, regressions were performed with the stock of hENs and the remaining ENs as the explanatory variables. The time period analysed in the study by the European Commission (2022) is between 1997 and 2017. The results reveal that hENs have a productivity effect at the economy-wide level and through value chains, but not at the sector-specific level. The coefficients for the hENs are also lower than those for the remaining ENs. In summary, the study by the European Commission (2022) shows that hENs have a productivity effect, but that the remaining ENs have an almost double productivity effect. Furthermore, the significant impact of hENs disappears when considering simultaneously the ENs. Complementary ENs have a higher productivity effect downstream in the value chain for both hENs and the remaining ENs. Since hENs are intended to fulfil other objectives, e.g., the protection of health, safety, and security, sometimes being contrary to productivity growth, their contribution to productivity growth is significantly lower than the remaining ENs (European Commission, 2022, p.47).

Complementary to productivity effects, the study of the European Commission (2022) also investigated whether there are systematic correlations between innovation activities and ENs using data of the Community Innovation Survey 2016.

The Community Innovation Survey (CIS) includes several variables that may be affected by ENs. The CIS explored two main areas of EN's impact on innovation: the diffusion of knowledge from standardisation, and the interplay between standardisation, legislation and innovation. In the study of the European Commission (2022) two variables are focusing on the numbers of firms that innovate per sector, and two variables focusing on the interplay between standardisation, legislation and innovation. The results show that sectors with more ENs also have a higher level of process innovations, which indicates that ENs have a positive impact on process innovation. However, the correlations with goods innovations and services innovations are not significant. When examining all types of innovations together, the results indicate that ENs are positively correlated with innovation within the sector.

In addition, ENs have more 'World first' innovations and more innovations which are new to the market, which is in line with the hypothesis that standards create a common ground from which to innovate. Moreover, the results show that sectors with more ENs have fewer innovations which are new only to the firm. A possible explanation for this is that ENs lead to more knowledge being

[356] European Commission (2022): Final report: Study on the functions and effects of European standards and standardisation in the EU and EFTA Member States and Annexes, https://ec.europa.eu/docsroom/documents/50114/attachments/1/translations/en/renditions/native.

disseminated within the sector, in turn leading the firm not to spend resources on making innovations that others already know, as the information is made available through ENs. Since correlations differencing between hENs and the remaining ENs are not displayed in the study of the European Commission (2022), we assume that they were not significant.

The CIS has several indicators on how legislation affects innovation. Primarily, these indicators focus on how legislation and regulation may adversely affect innovation. Since hENs often supplement legislation, therefore, they might hinder innovation. However, hENs are a softer way of legislating, which may make them a way of achieving government goals with less damage to innovation. Additionally, as previously mentioned, hENs may contribute to creating a common ground from which to innovate. To analyse how hENs may affect innovation, the study of the European Commission (2022) use data from CIS on how many firms state that their "innovation activities have been affected by legislation or regulations" by subject of the regulation/legislation that affects them. The legislation is divided into several subjects, of which four are relevant for this analysis: "Employment, worker safety or social affairs", "Environment", "Operational and worker safety" and "Product safety, consumer protection". For each of these, there is data on how big a percentage of firms answer that legislation/regulations result in "Stimulation of innovation", "Creation of uncertainty", "Generation of an excessive burden", "Lack of consistency across the EU", "No major problems caused" and "No impact".

There are two main hypotheses for how hENs should affect whether firms are affected by legislation. The first is that hENs constitute a form of regulation, and that sectors with more hENs should therefore have more firms answering they are affected by legislation. Under this hypothesis, we would expect that a higher level of harmonised standards in a sector would correlate with more firms answering that legislation creates uncertainty and a burden. The second hypothesis is that while hENs are related to legislation, they are a softer approach than the alternative and allow firms more freedom to find individual solutions and innovate. Under this hypothesis, sectors with many hENs are expected to have smaller adverse effects of regulation than sectors with few hENs do. Therefore, in sectors with many hENs, fewer firms would answer that legislation creates uncertainty, or an excessive burden. Further, fewer firms would answer that legislation creates a major problem.

In sectors with more hENs, fewer firms answer that legislation/regulation has "no impact" than in sectors with fewer hENs. In addition, they are more likely to answer that legislation causes "No major problems". In other words, these results indicate that firms in sectors with more hENs are more affected by legislation/regulation, but less likely to be majorly negatively affected by legislation. This would fit the first mentioned hypothesis: that hENs are a "soft" alternative to legislation, with less adverse effects on innovation. Overall, the stocks of hENs are no significant stimulus to innovation based on the CIS.

Assessment on the effects of options

In sections 5.2.1 and 6.2, we estimated the average duration expected in each option as a result of the policy measures assessed, as reported in the table 4.4 below.

Table 4.4: Summary of effects of policy option on average standardisation time

Total duration of each phase in years	Phase A: Policy phase	Phase B: Delivery phase	Phase C: Publication phase	Total average duration
Current situation	1,7	3,2	1,2	6,1

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Dynamic baseline	1,7	2,4	1,2	**5,3**
% reduction compared to current situation	***0%***	***-25%***	***0%***	***-13%***
Policy option 1 average	1,2	2,2	0,9	**4,3**
% reduction compared to dynamic baseline	***-29%***	***-7%***	***-28%***	***-19%***
Policy option 2 average	1,2	2,1	0,9	**4,2**
% reduction compared to dynamic baseline	***-28%***	***-13%***	***-28%***	***-21%***
Policy option 3 average	1,3	1,8	0,9	**4,0**
% reduction compared to dynamic baseline	***-25%***	***-24%***	***-28%***	***-25%***

We then assume that a reduction of the average duration of the standardisation process will result in an increased number of hENs available in a given amount of time (i.e. % of time reduction = % of stock of hEN increase). However, we cannot assume that this relationship is fully linear as there is an inherent complexity which prevents linearity in the growth of hENs. This complexity is affected by several factors:

- The capabilities to deliver standards depend primarily on the experts available, and the availability of experts is facing a demographic challenge (*cf.* Driver 2.2 in section 2.2)
- The number of hENs delivered depends on the number of Standardisation Requests issued by the European Commission which will continue in the next years regardless of the intervention
- Historically, from 2012 to 2025 the compound annual growth rate in the stock of hEN delivered is around 13%

We summarise these factors in a synthetic **complexity factor α = 0,2**, needed to scale down expectations of annual growth in hENs to a more realistic scenario. This isolates the effect of time reduction and ignores the fact that the number of hENs will increase based on the SRs the Commission will issue.

Table 4.5: Expected increase in hEN stock in the three options

Time reduction estimated in sections 5.2.1 and 6.2	**Option 1**	**Option 2**	**Option 3**
Average	19%	21%	25%
Average annual increase in the stock of hENs thanks to time reduction	**Option 1**	**Option 2**	**Option 3**
Average time * α = average annual increase in stock thanks to time reduction	3,8%	4,2%	5,0%

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Estimation of the impacts of harmonised European standards on GDP

Following the approach of the study by EU European Commission (2022), the standards valid in a country from 1990 to 2020 are used by Blind et al. (2026).[357]

The following countries are generally included in the country panel: Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Great Britain, Greece, Hungary, Ireland, Italy, Croatia, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden. However, NAUTOS only records the standards for 16 countries. The data was taken from the NAUTOS database, the successor to PERINORM[358]. Important to note, we can differentiate between national, European and international standards[359].

Following the approach of Jungmittag et al. (1999)[360], which has been replicated in numerous studies[361] and further developed[362], the basic model is based on a simple Cobb-Douglas production function:

$$Y_t = A_t K_t^{\alpha} L_t^{\beta} e^{\lambda t} \quad (1)$$

In the time series model, Y is the gross domestic product GDP or gross value added, K is capital and L is labor at time t in each case. Technical progress is modeled as a time trend in the form $A(t) = A_0 e^{\lambda t}$. In the Cobb-Douglas-model, the exponents α, β and λ can be interpreted as the respective production elasticities.[363] Technical progress is represented by various indicators. One measure of innovation in macroeconomic research is R&D expenditure, which is an input-based approach. However, it does not necessarily lead to innovative output, which is why a more output, strictly speaking, throughput-based measurement approach based on patents is also used.[364] Furthermore, it is not only innovations by domestic companies that contribute to technological progress in an economy. This is because they also use technologies and innovations from other companies and research institutions based abroad. License expenditure can be used as an indicator for this.

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[357] Blind, K., Neuhaeusler, P., Schubert, T., (2026) The economic effects of the quality infrastructure, Technology in Society, 84, 103114, https://doi.org/10.1016/j.techsoc.2025.103114.

[358] See https://www.beuth.de/de/normen-management/nautos.

[359] Blind, K.; Mangelsdorf, A.; Niebel, C. & Ramel, F. (2018): Standards in the global value chains of the European Single Market, Review of International Political Economy, 25:1, 28-48. Blind, K., Ramel, F. & Rochell, C. (2022): The influence of standards and patents on long-term economic growth. Journal of Technology Transfer 47, 979-999.

[360] Jungmittag, A., Blind, K., & Grupp, H. (1999): Innovation, standardization and the long-term innovation, standardization and the long-term production function. Journal of Economics and Social Sciences, 119, 205-222.

[361] ISO (2021): Standards & economic growth: ISO members' research on the impact of standards on their national economies https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100456.pdf

[362] Blind, K.; Jungmittag, A. (2008): The impact of patents and standards on macroeconomic growth: a panel approach covering four countries and 12 sectors, Journal of Productivity Analysis, vol. 29(1), 51-60. Blind, K., Ramel, F. & Rochell, C. (2022): The influence of standards and patents on long-term economic growth. Journal of Technology Transfer 47, 979-999.

[363] The production elasticity is the percentage change in the output quantity for a change in the input quantity of a production factor by an infinitesimally small percentage. It therefore approximates the percentage change in output for an input increase of 1 percent.

[364] Blind, K., Schubert, T. (2024): Estimating the GDP effect of Open Source Software and its complementarities with R&D and patents: evidence and policy implications The Journal of Technology Transfer 49 (2), 466-491.

First, the stock of standards with their impact dimensions is a key factor for measuring the economic impact of standards. Since - in contrast to patents - the knowledge specified in standards is generally not protected, they represent a publicly available pool of knowledge that can theoretically be used by all companies, but also by other organizations.

To estimate equation (1), it is converted into its logarithmic form. Lower case letters denote the natural logarithm of the variables, including α as the intercept value and u as the standard error term:

$$y_t = \alpha_0 + \alpha k_t + \beta l_t + \lambda t + u_t \quad (2)$$

If the time trend is replaced by the three indicators R&D expenditure, patents, license payments and different stocks of standards. Standards can be classified according to their regional scope. In general, a distinction can be made between national, regional and international standards. National standards are primarily developed by domestic market participants and therefore reflect domestic technological knowledge. They are tailored to the domestic economy. In addition, there are regional standards that are tailored to the preferences of certain economic regions, such as the EN. International standardisation bodies publish international standards that reflect the consensus of the players operating on the global market.

For the estimation, the standardization variable is defined by the stock of European standards eno.[365] the regression equation, now looks as follows:

$$y_{it} = \alpha_0 + \alpha k_{it} + \beta l_t + \lambda_1 rd_{it-1} + \lambda_2 pat_{it} + \lambda_3 lic_{it} + \lambda_4 eno_{it} + u_{it} \quad (3)$$

The results related to equation 3 are presented in Table 4.6. The total stock of ENs is significant. Moreover, they also have an important interpretation in terms of magnitude. The significant elasticity of 0.0122 on the stock of ENs indicates that a hypothetical 10% increase in the total stock of standards from 2019 to 2020 would contribute 0.122% of GDP in the EU.[366]

Table 4.6: Influence of standards on GDP[367]

	(1)
	Log GDP
Log population	-0.22691**
	(0.09191)
Log capital stock	0.19489***
	(0.03853)
L.Log R&D exp.	-0.02868
	(0.02415)
Log trans. patent appl.	0.16862***
	(0.01486)

[365] In the study on the benefits of European standards, a distinction was made between harmonized European standards and non-harmonized European standards (see also European Commission, 2022). However, this information is not available at country level.

[366] Here, we assume that the results of the 16 countries included in the panel are representative for the whole EU.

[367] Blind, K., Neuhaeusler, P., Schubert, T., (2026) The economic effects of the quality infrastructure, Technology in Society, 84, 103114, https://doi.org/10.1016/j.techsoc.2025.103114.

Log license payments	0.00000
	(0.00000)
Log stock eur. stds	0.01222*
	(0.00705)
Constant	28.34109***
	(1.61915)
Year dummies	Yes
Observations	347
R2	0.916
N_g	16

Standard error in brackets; * p < 0.10, ** p < 0.05, *** p < 0.01

Estimation of the impacts of harmonised European standards on innovation

As the contribution of standards to product and process innovations must also be taken into account, panel regressions based on time series data for countries were carried out[368], following the approach of Blind (2012) on the impact of regulation on innovation.[369]

As a first step, the country-specific number of firms with product and process innovations (inno) from the Community Innovation Survey is used as the dependent variable as in the study of the European Commission (2022). In a first step, quantification is carried out using a country panel model based on data from the countries mentioned above for the period from 1993 to 2020. Taking into account the differentiation in regulatory frameworks and the countries i, the final regression equation now takes the following form:

$$inno_{it} = \mathrm{a}_i + \alpha \mathrm{ex}_{it} + \beta im_{it} + \lambda_1 edu_{it} + \lambda_2 rd_{it-1} + \lambda_3 pat_{it} + \lambda_4 lic_{it} + \lambda_5 eno_{it} + u_{it} \quad (4)$$

Overall, the regression results in Table 4.7 show that the stock of ENs has no significant influence on the number of innovators in the EU. In the 2022 EU study (European Commission, 2022), only a correlation analysis was carried out, in which a significant coefficient was found only for process innovations.[370] Therefore, our results are in line with the previous study. Clearly, standards as a source of information have no significant influence on the number of innovators because they do not constitute an exclusive source of knowledge. Furthermore, standards are certainly also perceived as barriers to innovation, as studies based on company surveys have shown.[371] Overall, they have neither a positive nor a negative impact on innovation, as measured by the number of innovators. Since impacts of hENs might be closer to regulations, which can

[368] Blind et al. (2025): Die Bedeutung der Qualitätsinfrastruktur: Studie zu wirtschaftlichen und nicht-wirtschaftlichen Wirkungen sowie Trendstudie Digitalisierung. Endbericht10.24406/publica-4411

[369] Blind, K. (2012): The influence of regulations on innovation: A quantitative assessment for OECD countries, Research Policy, Volume 41, Issue 2, 391-400, https://doi.org/10.1016/j.respol.2011.08.008.

[370] Blind, K.; Münch, F. (2024): The interplay between innovation, standards and regulation in a globalising economy, Journal of Cleaner Production, 445, 141202, https://doi.org/10.1016/j.jclepro.2024.141202. They use R&D expenditure and patent applications as indicators of innovation and find that, for a larger panel of OECD countries, international standards have a positive impact, whereas national standards tend to hinder innovation.

[371] Blind, K., Petersen, S.S., Riillo, C. A. F. (2017): The impact of standards and regulation on innovation in uncertain markets, Research Policy, 46(1), 249-264, https://doi.org/10.1016/j.respol.2016.11.003.

hinder innovation, this insignificant result could be considered as optimistic assessment. Since we cannot observe a significant impact of hEN, we do not present a table with the impacts of the policy options.

Table 4.7: Influence of Standards on Innovation[372]

	(1)
	Log #innovative firms
Log exports	-0.16881
	(0.30578)
Log imports	0.82314**
	(0.31431)
Log share tert. educ. empl.	0.09491
	(0.23972)
Log R&D exp.	-0.39677*
	(0.20322)
Log trans. patent appl.	-0.02927
	(0.12409)
Log license payments	-0.00000
	(0.00000)
Log stock eur. norms	-0.03644
	(0.08229)
Constant	-2.40783
	(5.91334)
Year dummies	Yes
Observations	102
R2	0.746
N_g	16

Standard errors in brackets; * p < 0.10, ** p < 0.05, *** p < 0.01

Estimation of the impacts of harmonised European standards on export

In addition to the effects of standards on economic development, its impact on international competitiveness—and thus on exports—is particularly relevant[373].

The estimation model used to determine the effects of standards on trade follows Blind et al. (2021, 2025)[374] and is defined as follows. The dependent variable takes the values of exports *ex.*

[372] Blind et al. (2025): Die Bedeutung der Qualitätsinfrastruktur: Studie zu wirtschaftlichen und nicht-wirtschaftlichen Wirkungen sowie Trendstudie Digitalisierung. Endbericht10.24406/publica-4411

[373] See Swann, G. (2010): International Standards and Trade: A Review of the Empirical Literature, OECD Trade Policy Papers, No. 97, OECD Publishing, Paris. http://dx.doi.org/10.1787/5kmdbg9xktwg-en.

[374] Blind et al. (2021). The impact of Open Source Software and Hardware on technological independence, competitiveness and innovation in the EU economy, Final Study Report. European Commission Brussels. Blind

A model of trade flows from the EU country *i* to the rest of the world (ROW) at time *t* is estimated, which is explained by the various types of standards, taking control variables into account.

The influence of the different stocks of standards on exports is determined using the following estimation equation:

$$ex_{it} = \mathrm{a}_i + \lambda_1 \mathrm{gdp}_{it} + \lambda_2 gdpWorld_t + \lambda_3 rd_{it} + \lambda_4 rdWorld_t + \lambda_5 pat_{it} + \lambda_6 lic_{it} + \lambda_7 eno_{it} + u_{it} \quad (5)$$

The results of the estimates in Table 4.8 confirm the positive effects of ENs found in earlier studies.[375] The significant elasticity of 0.0632 on the stock of ENs indicates that a hypothetical 10% increase in the total stock of standards from 2019 to 2020 would contribute 0.632% to the exports of the EU member states.

Table 4.8: Influence of Standards on Exports[376]

	(1) Log exports
Log GDP	1.23128***
	(0.10460)
Log GDP (World)	2.16269
	(39.74341)
Log R&D exp.	-0.01101
	(0.04675)
Log R&D exp. (World)	-1.39762
	(28.29628)
Log trans. patent appl.	0.13705***
	(0.03206)
Log license payments	0.00000**
	(0.00000)
Log stock eur. norms	0.0632***
	(0.01147)
Constant	-52.01854
	(758.53884)
Year dummies	Yes
Observations	360
R2	0.935
N_g	16

Standard errors in brackets; * p < 0.10, ** p < 0.05, *** p < 0.01

et al. (2025): Die Bedeutung der Qualitätsinfrastruktur: Studie zu wirtschaftlichen und nicht-wirtschaftlichen Wirkungen sowie Trendstudie Digitalisierung. Endbericht10.24406/publica-4411

[375] Blind, K.; Mangelsdorf, A.; Niebel, C. & Ramel, F. (2018). Standards in the global value chains of the European Single Market, Review of International Political Economy, 25:1, 28-48.

[376] Blind et al. (2025): Die Bedeutung der Qualitätsinfrastruktur: Studie zu wirtschaftlichen und nicht-wirtschaftlichen Wirkungen sowie Trendstudie Digitalisierung. Endbericht10.24406/publica-4411

ANNEX 5: COMPETITIVENESS CHECK

1. OVERVIEW OF IMPACTS ON COMPETITIVENESS

Dimensions of Competitiveness	Impact of the initiative (++ / + / 0 / - / -- / n.a.)	References to sub-sections of the main report or annexes
Cost and price competitiveness	+	6.2, 6.3, 6.4, 6.5
International competitiveness	+	6.2, 6.4, 6.5
Capacity to innovate	+	6.2, 6.5
SME competitiveness	+	6.2, 6.3, 6.4, 6.5

2. SYNTHETIC ASSESSMENT

Costs and price competitiveness

The preferred option, policy option 2, implies significant compliance cost savings for businesses using hENs. First, the faster availability of hENs is estimated to generate annual savings of approximately EUR 295 million through reduced costs for conformity assessments and related compliance procedures. Second, the provision of free access to standards is expected to generate additional savings of around EUR 30 million for businesses. These savings correspond to revenues currently earned by National Standardisation Bodies (NSBs) from the sale of hENs, which would instead remain with companies under the proposed free-access regime.

International competitiveness

The increased use of hENs – developed not only by ESOs but also by alternative SDOs – could be particularly valuable for fast-moving technologies where ESOs may lack the necessary expertise. If these new hENs are delivered in a timely manner, the EU industry could gain a first-mover advantage in introducing new products and services. A more agile European Standardisation System could thus help the EU strengthening its influence over international standardisation processes and further harmonising market requirements between the EU and international partners. While these hENs might not always reduce costs or prices for implementing companies, they have the potential to drive innovation if designed in an innovation-friendly way. Over time, this could enhance the EU industry's innovativeness compared to international competitors, ultimately improving its overall competitiveness.

Additionally, the swift development of hENs, alongside better coordination among EU stakeholders in international standardisation bodies, would benefit export-driven EU companies by ensuring closer alignment between EU and global standards. This would simplify access to third-country markets, as businesses could rely on European standards to meet international requirements, thereby reducing non-tariff trade barriers.

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However, the provision in the preferred option for the EU to exercise strategic autonomy in specific cases might reduce international competitiveness in the affected sectors due to potential misalignment between EU and global standards. On the other hand, it could indirectly boost the competitiveness of EU firms in those sectors by securing a domestic technological foundation based on European standards – and projecting that influence internationally.

Capacity to innovate

Free access to hENs could trigger a positive impact on product or process innovation by facilitating integration of standards close to the state of the art into new products' development. The faster availability of hENs introduced by the preferred option should not have direct impact on the capacity of EU's companies to carry out R&D, or to generate Intellectual Property Rights, like patents, as such positive relations could not be observed in the past. However, faster availability of standards and standardisation deliverables, coupled with the improved participation of the research community in the standardisation process, could improve the diffusion of innovation as standards allow research and innovation results to spread into market-ready solutions. Moreover, in some sectors the savings on conformity assessment and the free availability of hENs may free up more resources for companies to invest in research and innovation.

SME competitiveness

SME will benefit from all three dimensions of the positive impacts of the preferred option on competitiveness.

SMEs will benefit relatively more than larger firms from a more responsive ESS, as the gains in compliance costs represent a larger proportion of their costs. This will contribute to level the playing field between SMEs and larger undertakings as the latter are generally more able to absorb higher compliance costs due to larger economies of scale and can thus access markets more easily even when hENs are not available. In addition, the preferred option introduces measures that will facilitate SME's participation to standardisation process. This will help SMEs promote their specific interest and ensure that standards are designed closer to their needs, as well as increase the legitimacy and acceptability of standards by SMEs. The measure may however increase participation costs for SMEs when hENs are requested to alternative SDOs, in which they are less likely to be already involved.

SMEs competitiveness should also be improved by the increased EU influence in international standardisation coupled with the strong alignment between EU and international standards. This will reduce barriers to trade and facilitate SMEs' access to third country markets.

SMEs' capacity to innovate should also be impacted favourably by the preferred option, both through the ability to get faster access to standards in key technology areas and through the free access to hENs, which could foster diffusion of innovation. Having free and facilitated access to draft hENs will also allow SMEs to better anticipate the implementation of new technical solutions, hence being able to plan and adapt accordingly.

3. COMPETITIVE POSITION OF THE MOST AFFECTED SECTORS

This initiative is horizontal in nature since the Standardisation Regulation affects many different sectors relying on hENs. Considering the existing stock of hENs, together with

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currently planned standardisation requests, the most affected sectors are reported in the following table (according to Eurostat data[377]).

While all enterprises in sector supported by the Standardisation Regulation could be potential beneficiaries of the preferred option, a conservative estimate would be that immediate direct benefits (compliance costs savings) could be expected for 7 % of businesses. This derived from the fact that the annual number of single downloads of hENs in 34 NSBs is 584 800[378], which represents around the 7 % of the total number of enterprises in concerned sectors. This is likely an underestimation of the potential number of direct and indirect users of hENs because many NSBs have a subscription-based model, giving access to a bundle of standards, which are not counted in the single downloads. While this underestimation was needed to have a more robust figure of direct costs savings, it should be expected that potentially affected enterprises will be much higher in the medium – long term.

Sector	Number of enteprises in EEA	Number of SMEs in EEA	% SMEs
Computer programming, consultancy and related activities	1.028.996	1.023.093	99,4%
Manufacture of machinery and equipment n.e.c.	79.870	77.766	97,4%
Construction	4.133.101	4.115.640	99,6%
Manufacture of electrical equipment	41.272	40.331	97,7%
Manufacture of wearing apparel	131.071	130.852	99,8%
Manufacture of transport equipment n.e.c.	3.986	3.932	98,6%
Manufacture of medical and dental instruments and supplies	61.752	61.410	99,4%
Manufacture of basic pharmaceutical products	957	155	16,2%
Manufacture of railway locomotives and rolling stock	748	496	66,3%
Manufacture of tanks, reservoirs and containers of metal	4.269	4.205	98,5%
Manufacture of basic chemicals, fertilisers and nitrogen compounds [...]	8.732	8.414	96,4%
Manufacture of other general-purpose machinery	32.089	27.904	87,0%
Postal activities under universal service obligation	7.514	1.010	13,4%
Manufacture of games and toys	8.621	7.492	86,9%
Manufacture of other chemical products	6.182	6.022	97,4%
Technical testing and analysis	86.546	86.151	99,5%
Building of ships and boats	9.310	9.210	98,9%
Manufacture of instruments and appliances for measuring, testing etc.	10.734	10.449	97,3%
Manufacture of domestic appliances	3.308	2.960	89,5%
Manufacture of plastics products	47.878	46.862	97,9%
Manufacture of soap and detergents, cleaning and polishing preparations [...]	13.183	12.937	98,1%
Manufacture of rubber products	7.824	7.631	97,5%
Manufacturing (generic, excluding already listed sectors)	1.716.374	1.712.259	99,8%
Total	**7.444.317**	**7.397.181**	**99,4%**

The implementation of the preferred option, leading to a significant increase in the timely production of hENs, will mostly benefit the sectors with the highest stock of hENs. The sectors with the most hENs are “Manufacturing of Electrical equipment”, “Machinery”, and “Construction”, while “Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations”, “Manufacture of rubber products” and “IT and information services” had the fewest.

The implementation of Option 2 will help increasing international competitiveness via the timely production of hENs and increased coordination among EU actors leading to more EU influence on international standardisation. Exporting sectors, such as machinery & vehicles,

[377] Enterprise statistics by size class and NACE Rev. 2 activity (from 2021 onwards)
[378] These data were collected for the first time in this Study through interviews with 17 NSBs, which on average claimed that annual downloads of hENs amount at 17.200. This figure was multiplied by 34 to obtain a total average number. These figures were validated in the “reality check” workshop with NSBs.

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chemicals & pharmaceuticals, and other manufactured goods, are expected to benefit most. The preferred option could also lead to EU companies gaining a competitive advantage compared to non-EU competitors in strategic technological sectors through faster availability of standards closer to the state of the art, for instance in AI, cyber-resilience or quantum technologies.

Finally, taking the investment in R&D as an indicator for innovation displayed by the R&D Scoreboard, EU companies in the health and energy sectors would benefit most due to increasing R&D investments. The EU ICT sector might also benefit from an innovation-friendly implementation of Option 2, notably the new possibility to rely on alternative SDOs that are closer to the state of the art in these highly innovative fields and that could deliver hENs faster and closer to market needs.

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ANNEX 6: SME CHECK

OVERVIEW OF IMPACTS ON SMES

Relevance for SMEs
Based on the SME filter and the ISCG discussion, this initiative is relevant for SMEs, as they represent 99% of companies in the key sectors supported by the Standardisation Regulation.

(1) IDENTIFICATION OF AFFECTED BUSINESSES AND ASSESSMENT OF RELEVANCE
Are SMEs directly affected? *(Yes/No)* **In which sectors?**
Yes, SMEs are directly affected by the initiative, across all sectors supported by the Standardisation Regulation.
Estimated number of directly affected SMEs
The sectors most likely to be affected have been identified together with their respective share of SMEs, based on the existing stock of hENs. These sectors account for approximately 7.4 million SMEs in total. Although all SMEs operating in these sectors could potentially be affected by the initiative, a lower-bound estimate suggests that around 550 000 SMEs are likely to benefit most directly from the resulting cost savings[379]. ***Table 6.1: Number of affected SMEs per sector (NACE rev.2)***

[379] This estimate corresponds to approximately 7 % of the total number of SMEs operating in the identified sectors. The percentage is derived by comparing the annual number of downloads of harmonised European standards the total number of firms active in those sectors. It assumes that the proportion of firms downloading hENs each year provides a reasonable proxy for the share of SMEs likely to be directly affected by, or making active use of, harmonised standards.

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Sector	Micro	Small	Medium	Total
Manufacturing (generic, excluding sub-sectors listed below)	1.482.075	189.953	40.231	1.712.259
Manufacture of wearing apparel	119.073	10.083	1.696	130.852
Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	5.798	1.686	930	8.414
Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	10.730	1.550	657	12.937
Manufacture of other chemical products	4.096	1.310	616	6.022
Manufacture of basic pharmaceutical products	16	6	133	155
Manufacture of rubber products	5.639	1.501	491	7.631
Manufacture of plastics products	31.341	11.019	4.502	46.862
Manufacture of tanks, reservoirs and containers of metal	2.716	1.089	400	4.205
Manufacture of instruments and appliances for measuring, testing and navigation; watches and clocks	7.105	2.326	1.018	10.449
Manufacture of electrical equipment	30.523	7.009	2.799	40.331
Manufacture of domestic appliances	2.456	492	12	2.960
Manufacture of machinery and equipment n.e.c.	50.572	19.831	7.363	77.766
Manufacture of other general-purpose machinery	21.463	3.670	2.771	27.904
Building of ships and boats	7.651	1.198	361	9.210
Manufacture of railway locomotives and rolling stock	363	7	126	496
Manufacture of transport equipment n.e.c.	3.195	546	191	3.932
Manufacture of games and toys	7.027	362	103	7.492
Manufacture of medical and dental instruments and supplies	54.275	6.205	930	61.410
Construction	3.872.854	221.388	21.398	4.115.640
Postal activities under universal service obligation	1.008	1	1	1.010
Computer programming, consultancy and related activities	975.297	38.779	9.017	1.023.093
Technical testing and analysis	80.599	4.607	945	86.151
Total	**6.775.872**	**524.618**	**96.691**	**7.397.181**

Source: Eurostat Enterprise statistics by size class and NACE Rev. 2 activity (from 2021 onwards); data for 2024, and, where unavailable, from the most recent year available.

Estimated number of employees in directly affected SMEs

The initiative is expected to affect sectors in which SMEs employ more than 31 million people in total (Table 2). The number of employees in SMEs directly affected, i.e. actually using hENs, would be 2 million[380].

Table 6.2: Number of affected employees in SMEs per sector (NACE rev.2)

Sector	Micro	Small	Medium	SMEs total
Manufacturing (generic, excluding sub-sectors listed below)	2.964.946	3.748.631	4.040.624	10.754.201
Manufacture of wearing apparel	196.018	197.112	168.815	561.945
Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	12.300	40.053	101.382	153.735

[380] Eurostat Enterprise statistics by persons employed, size class and NACE Rev. 2 activity (from 2021 onwards). Data from 2024 and, where unavailable, from the most recent year available.

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Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	19.760	33.993	69.374	123.127
Manufacture of other chemical products	9.922	29.595	66.210	105.727
Manufacture of basic pharmaceutical products	1.228	3.920	15.409	20.557
Manufacture of rubber products	13.098	30.539	47.910	91.547
Manufacture of plastics products	81.238	249.109	472.198	802.545
Manufacture of tanks, reservoirs and containers of metal	7.406	23.815	42.440	73.661
Manufacture of instruments and appliances for measuring, testing and navigation; watches and clocks	17.932	51.415	109.436	178.783
Manufacture of electrical equipment	64.447	154.144	301.843	520.434
Manufacture of domestic appliances	4.754	11.415	29.470	45.639
Manufacture of machinery and equipment n.e.c.	134.484	432.557	797.662	1.364.703
Manufacture of other general-purpose machinery	54.249	160.766	293.324	508.339
Building of ships and boats	14.972	24.400	33.863	73.235
Manufacture of railway locomotives and rolling stock	858	3.887	14.978	19.723
Manufacture of transport equipment n.e.c.	5.778	11.013	20.698	37.489
Manufacture of games and toys	9.196	7.371	10.416	26.983
Manufacture of medical and dental instruments and supplies	112.630	115.546	96.977	325.153
Construction	6.660.361	4.054.726	1.944.851	12.659.938
Postal activities under universal service obligation	2.033	400	727	3.160
Computer programming, consultancy and related activities	1.200.429	815.867	909.942	2.926.238
Technical testing and analysis	130.463	90.183	94.455	315.101
Total	**11.718.502**	**10.290.457**	**9.683.004**	**31.691.963**

The proportion of employment in SMEs corresponds, on average, to around 61% of total employment in the sectors covered by the Standardisation Regulation (Table 3)[381].

Table 6.3: Proportion of affected employment in SMEs per sector (NACE rev.2)

Sector	Micro	Small	Medium	SMEs total
Manufacturing (generic, excluding sub-sectors listed below)	15%	19%	20%	54%
Manufacture of wearing apparel	28%	28%	24%	80%

[381] Eurostat Enterprise statistics by persons employed, size class and NACE Rev. 2 activity (from 2021 onwards). Proportions were calculated as the number of persons employed in SMEs divided by the total number of persons employed in SMEs and large enterprises. Data from 2024 and, where unavailable, from the most recent year available.

Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	2%	7%	18%	27%	
Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	7%	12%	24%	42%	
Manufacture of other chemical products	5%	14%	31%	49%	
Manufacture of basic pharmaceutical products	1%	4%	16%	22%	
Manufacture of rubber products	4%	10%	16%	31%	
Manufacture of plastics products	6%	17%	33%	56%	
Manufacture of tanks, reservoirs and containers of metal	6%	20%	36%	62%	
Manufacture of instruments and appliances for measuring, testing and navigation; watches and clocks	4%	11%	23%	37%	
Manufacture of electrical equipment	4%	10%	19%	33%	
Manufacture of domestic appliances	2%	5%	13%	20%	
Manufacture of machinery and equipment n.e.c.	4%	14%	25%	43%	
Manufacture of other general-purpose machinery	5%	15%	28%	48%	
Building of ships and boats	8%	13%	18%	39%	
Manufacture of railway locomotives and rolling stock	1%	3%	11%	15%	
Manufacture of transport equipment n.e.c.	8%	16%	29%	53%	
Manufacture of games and toys	16%	13%	18%	47%	
Manufacture of medical and dental instruments and supplies	19%	19%	16%	54%	
Construction	46%	28%	13%	87%	
Postal activities under universal service obligation	0%	0%	0%	0%	
Computer programming, consultancy and related activities	25%	17%	19%	61%	
Technical testing and analysis	24%	17%	18%	59%	
Total	**23%**	**20%**	**19%**	**61%**	

Are SMEs indirectly affected? *(Yes/No)* **In which sectors? What is the estimated number of indirectly affected SMEs and employees?**

SMEs are also indirectly affected by the initiative; the same number of SMEs are directly and indirectly affected.

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(2) CONSULTATION OF SME STAKEHOLDERS

How has the input from the SME community been taken into consideration?

SMEs and their representatives took part to several consultation activities, conducted between June 2025 and May 2026, including:

- The call for evidence launched on the Have your say portal between 23 June 2025 - 21 July 2025.
- The public consultation opened between from 24 September to 17 December 2025 (69 SMEs replies).
- One targeted online survey for industry organisations and companies, including SMEs, to gather specific feedback on costs and benefits to be expected from the different options (87 replies from SMEs: 30 micro, 20 small, and 27 medium enterprises).
- One in-depth interview with SBS, the Annex 3 organisation representing the interests of SMEs in European standardisation.
- One workshop with 30 SMEs and their EU representative organisations held on 27 March 2026.

Are SMEs' views different from those of large businesses? *(Yes/No)*

SMEs' views expressed throughout the consultation for the initiative have not been different from those expressed by the business community in general. Replies in the OPC and the targeted surveys showed a high-level of alignment, both as regards the identification of problems and as regards the preferred policy measures to implement.

On some specific measures, consensus among SMEs is higher than among large enterprises, while still being aligned with the rest of the industry. In the OPC, 70 % of SMEs either strongly or somewhat agree to the need to introduce flexibility in the way hENs are developed and delivered, through both dedicated and simplified formats and procedures and the use of alternative types of deliverables instead of standards. In addition, 60 % of SMEs either strongly or somewhat agree to enforce stronger mechanisms such as mandatory deadlines paired with penalties, to enforce timely delivery of requested (harmonised) standards. 63 % of SMEs either strongly or somewhat agree to reinforce voting rights for SMEs, consumers and other societal stakeholders (Annex III) in the standardisation process.

On the measure to introduce binding legal obligations on NSBs for the involvement of SMEs and societal stakeholders by revising the provisions in Art. 6, the share of SMEs expecting higher benefits is higher than the share of large enterprises. In the targeted survey to industry organisations and companies, 65 % of SME respondents expected high or very high benefits from this measure, compared with 36 % of respondents from large enterprises.

Regarding the support for the participation of experts in technical committees, 89 % of SMEs either strongly or somewhat agree; SMEs even show a unanimous support towards financial support and capacity building to improve participation of experts representing SMEs or civil society from the EU in technical committees at the international level.

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(3) ASSESSMENT OF IMPACTS ON SMEs[382]
What are the estimated direct costs for SMEs of the preferred policy option?
Qualitative assessment
The preferred policy option is expected to generate very limited direct costs for SMEs. The flexibility for the Commission to request hENs to alternative SDOs may lead to increased participation costs for SMEs that are willing to participate to the standardisation process, if they are already active in similar standardisation activities within ESOs. SMEs active in the sectors where a derogation from the 'international first' principle would be applied would be affected similarly as other businesses in the sector.
Quantitative assessment
There is no available data to quantify the potential additional costs for SMEs of participation to the standardisation process conducted by alternative SDOs.
What are the estimated direct benefits/cost savings for SMEs of the preferred policy option[383]?
Qualitative assessment
The preferred option is expected to generate substantial direct benefits and cost savings for SMEs. The main benefits include: • **Faster availability of harmonised standards**, enabling SMEs to reduce conformity assessment costs (compliance costs) and to access sooner the internal market, levelling the playing field with larger businesses that can generally afford higher compliance costs (notably through conformity assessment not based on a hEN) due to higher economies of scale. • **Reduced costs for purchasing standards**, due to free and unrestricted access to the harmonised standards. Although the costs of a hEN is not identified as a financial barrier, SMEs may benefit from this saving as well as from the possibility to access the full catalogue of hEN. • **Improved participation and representation** in standardisation through binding obligations on National Standardisation Bodies (NSBs) that should further reduce the costs for SMEs to participation in the standardisation process conducted by ESOs. • **Improved access to international markets**, thanks to the increased EU influence at international level that should lead to overall increased alignment between hENs and international standards and lower costs for SMEs to access both the EU and the international markets.

[382] The costs and benefits data in this annex are consistent with the data in annex 3. The preferred option includes the mitigating measures listed in section 4.
[383] The direct benefits for SMEs can also be cost savings.

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Quantitative assessment
The estimated total savings in compliance costs of EUR 295 million generated by the preferred option will benefit in majority SMEs. Considering that SMEs usually develop less products and require less conformity assessments that large undertakings, they will benefit from a lower share than the 99 % of the number of beneficiaries they represent. While there is no data to estimate the average number of conformity assessments conducted by SMEs and large undertakings, one indicator from the Impact Assessment on the revision of the NLF[384] provide an estimate of the relative difference between SMEs and large undertakings. Large undertakings develop 28 times more new models requiring separate declarations of conformity than SMEs (100 per year vs. 3.5 per year)[385]. This would lead to SMEs benefitting from 78 % of the savings in compliance costs generated by the preferred option (EUR 230 million). The savings generated by the preferred option through free access to standards cannot be differentiated between SMEs and large undertakings, as there is no information on their respective weight in hENs. Assuming the same repartition as for savings from conformity assessment, this would generate additional savings of EUR 23 million for SMEs.
What are the indirect impacts of this initiative on SMEs? *(Fill in only if step 1 flags indirect impacts)*

(4) MINIMISING NEGATIVE IMPACTS ON SMES
Are SMEs disproportionately affected compared to large companies? (*Yes/No)* **If yes, are there any specific subgroups of SMEs more exposed than others?**
The preferred option does not negatively impact disproportionately SMEs compared to large companies. The specific subgroup of SMEs that could be more exposed than others are the ones that are actively engaged in standardisation activities within ESOs in a given sector for which the Commission would request a hEN from an alternative SDOs. This could limit the ability of these SMEs to influence the standardisation process in the alternative SDOs and could create additional costs for them to transfer their standardisation participation to the alternative SDO.
Have mitigating measures been included in the preferred option/proposal? (Yes/No)
Mitigating measures have been included in the preferred option to ensure that the standardisation process from an alternative SDO would remain inclusive and would allow voluntary SMEs to participate. Consulted SMEs representatives were not fully confident that the level of inclusiveness offered by ESOs would be ensured by other SDOs. The preferred option includes two mitigating measures. First, the Commission could only rely on alternative SDOs meeting pre-defined criteria that ensure a highly inclusive process, based on the WTO TBT principles for standardisation and on the current Annex II of the

[384] Impact Assessment on the revision of the New Legislative Framework [to be published].
[385] Estimates based on a survey to industry, based on 10 SME respondents and 100 large undertakings respondents.

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Standardisation Regulation applying to ICT technical specifications from alternative SDOs. Second, the Commission, depending on the sector and the actual hEN requested to alternative SDOs, could include *ad hoc* requirements on inclusiveness of SMEs as a pre-condition in the standardisation request, depending on the sector.

CONTRIBUTION TO THE 35% BURDEN REDUCTION TARGET FOR SMES
Are there any administrative cost savings relevant for the 35% burden reduction target for SMEs?
Yes, SMEs will benefit from the administrative burden reduction identified in Annex 3, which will benefit all businesses equally.

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ANNEX 7: SCOPE OF THE STANDARDISATION REGULATION AND OF THE PROPOSED POLICY INTERVENTION

1. STANDARDS SUPPORTING UNION LEGISLATION AND POLICY

1.1. Standards developed under the Standardisation Regulation

Regulation (EU) No 1025/2012[386] (hereafter the 'Regulation') provides a legal basis for using European standardisation as a policy tool to support EU legislation and policies for products and for services. It organises the legal interface between the Commission, the European standardisation organisations (ESOs) as defined in its Annex I[387] (CEN, CENELEC and ETSI) and the national standardisation bodies (NSBs), regarding **standards and standardisation deliverables requested in support of EU law and policies**.

There are **2 main types of standards or standardisation deliverables of ESOs**[388] covered by the Standardisation Regulation:

1. The focus of the Standardisation Regulation is **delivering harmonised standards**, which are European standards adopted by one or more ESOs, following a request from the European Commission to support Union harmonisation legislation. Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in relevant Union harmonisation legislation, its references must be published in the Official Journal of the European Union (OJEU) by the Commission, or by other means (like e.g. addition to an Annex via secondary legislation) in accordance with the conditions laid down in the corresponding legal act – see Annex 8.
2. The Regulation also allows the Commission to request standards or standardisation deliverables from the ESOs ***"in support of Union policy and legislation"***, without necessarily providing presumption of conformity to the standard or any direct legal

[386] Regulation (EU) 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJ L 316, 14 November 2012, p. 12-33.

[387] As recognised in the regulation the ESOs are the European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (Cenelec) and European Telecommunications Standards Institute (ETSI).

[388] The Standardisation Regulation defines "standardisation deliverable" as "*any other technical specification than a European standard, adopted by a European standardisation organisation for repeated or continuous application and with which compliance is not compulsory*" (Article 2(2)). In practice, standardisation deliverables are agreements adopted by standardisation organisation with differing level of transparency, consensus and approval than a full-fledge standard. They can be intermediate step to the adoption of a standard. For instance, CEN deliverables include notably, CEN Technical Specification (CEN/TS), that serves as normative document in areas where the actual state of the art is not yet sufficiently stable for a European Standard; CEN Technical Report (CEN/TR), for information and transfer of knowledge; or CEN Workshop Agreement (CWA), which aims at bringing about consensual agreements based on deliberations of open Workshops with unrestricted direct representation of interested parties. See CEN Deliverables. CENELEC has a similar typology (Development of CENELEC Homegrown Deliverables). ETSI develops more different deliverable, but follows a similar approach, distinguishing standards and technical specifications (Understanding standards - ETSI).

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effect, the Commission determining in its request "*the requirements as to the content to be met by the requested document*"[389].

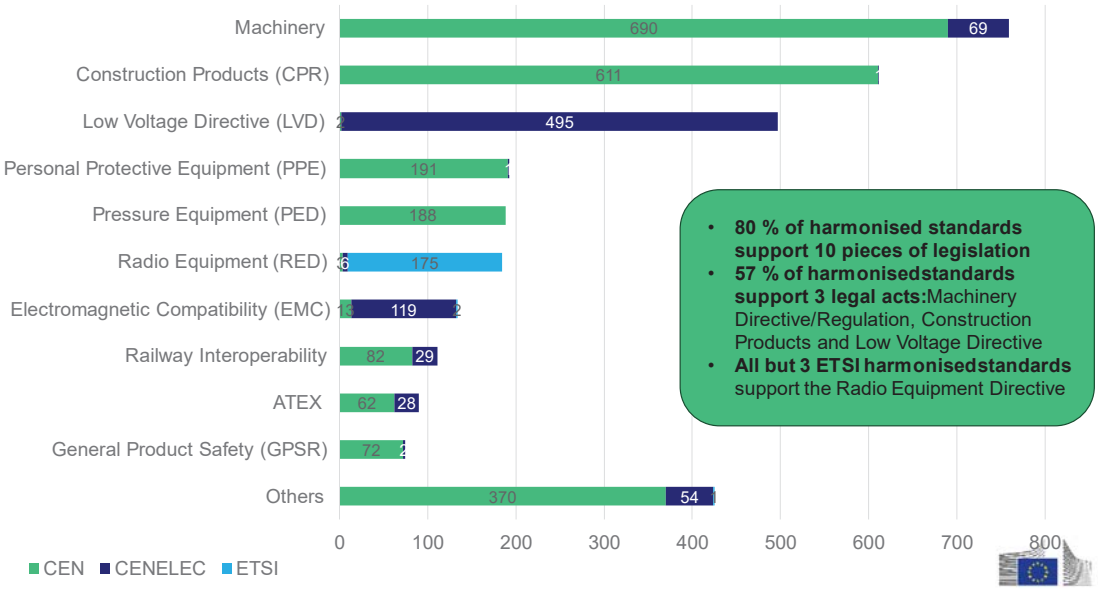
The Standardisation Regulation thus organises the *ex ante* development of standards and standardisation deliverables by the European standardisation organisations[390]; the legislative need for a standard precedes the existence of the standard, whose development the Commission requests to the ESOs. The Regulation also calls to ensure the effectiveness and efficiency of standards and standardisation as policy tools for the Union through cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission.

The delivery of harmonised standards primarily supports **Union legislation under the New Legislative Framework (NLF)[391]**, a body of 30 pieces of EU legislation regulating the internal market for goods and services that rely on harmonised standards to provide a presumption of conformity. More recently, an increasing number of sectoral legislations have come to rely on the Standardisation Regulation to deliver harmonised standards that provide a presumption of conformity. This includes notably the Data Act, the AI Act and the Cyber Resilience Act to support EU digital transition – see below for an overview of the legislation and policies supported by the Standardisation Regulation[392].

As of 31 March 2026, more than 3 270 standards requested from ESOs have been adopted and cited by the Commission. Standards from CEN/CENELEC make up the majority of these standards (95 % of the total). Most of these standards and standardisation deliverables support ten pieces of Union legislation, together accounting for 80 % of the harmonised standards cited in the OJEU. Standards supporting the Machinery and Low Voltage Directives alone make up close to 50 % of the total standards cited[393]. In addition, there are 178 harmonised standards from ETSI, supporting mainly the Radio Equipment Directive. See below for a detailed overview of Union legislation supported by harmonised standards.

Portfolio of harmonised standards by Union legislation

[389] Article 10(1) of the Standardisation Regulation.
[390] The Regulation also established rules to identifying ICT technical specifications developed by other standard development organisations other than the ESOs or international standardisation bodies, which may be referenced in public procurement, primarily to enable interoperability. For instance, at the end of 2024, the Commission initiated the identification process of ICT technical specifications to be referenced in implementing acts related to the European Digital Identity (eIDAS) Regulation.
[391] New legislative framework - Internal Market, Industry, Entrepreneurship and SMEs
[392] Based on the Evaluation of the Standardisation Regulation, p. 24-25.
[393] CEN CENELEC in figures - Quarterly, 2026 Q1



List of legislation and policy relying on the Standardisation Regulation

Legislation from the NLF	Legislation referring to Standardisation Regulation	Other legislation and policy initiatives relying on the Regulation
Toy Safety Regulation	Critical Raw Materials Act	European Green Deal
Transportable pressure equipment Directive	Net Zero Industry Act	Circular Economy Action Plan
Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive	Hydrogen Regulation	Clean Industrial Deal
Construction products Regulation	Data Act	Digital Decade
Pyrotechnic Articles Directive	General Product Safety Regulation	NIS2
Recreational craft and personal watercraft Directive	Energy Labelling Regulation	Cyber Security Act (CSA)
Civil Explosives Directive	Cosmetic products Regulation	Digital Service Act (DSA)
Simple Pressure Vessels Directive	REACH Regulation	European Digital Identity
Electromagnetic Compatibility Directive	Interoperability of the rail system Regulation	Financial Data Access
Non-automatic Weighing Instruments Directive	Inspection of pesticide application equipment	Interoperable Europe Act
Measuring Instruments Directive	Accessibility of the websites and mobile applications of public sector bodies (WAD)	Intelligent Transport System (ITS
Lifts Directive	Plastic caps and lids	Web 4.0 and virtual worlds strategy
ATEX Directive	Community eco-management and audit scheme (EMAS)	EU action Plan for Grids.
Radio equipment Directive	Active implantable medical devices	Multimodal Digital Mobility Services
Low Voltage Directive	Postal Services Directive	Critical Raw Materials Act
Pressure equipment Directive		
Marine Equipment Directive		
Cableway installations Regulation		
Personal protective equipment Regulation		
Gas appliances Regulation		
Medical devices Regulation		
In vitro diagnostic medical devices Regulation		
EU fertilising products Regulation		
Drones / unmanned aircraft systems Commission Delegated Regulation		
Batteries Regulation		
Machinery Regulation		
Ecodesign requirements for sustainable products Regulation		
Artificial Intelligence Act Regulation		
Cyber Resilience Act Regulation		
Packaging and Packaging Waste Regulation		

1.2. Standards directly referenced in Union legislation

EU legislation can also reference standards outside of the framework of the Standardisation Regulation. A large array of EU secondary legislation directly references standards from ESOs, international standardisation bodies or other standardisation organisations. Such "directly referenced standards" can have an indicative value, providing an example of how to comply with certain legal obligations, or can be mandatory. Direct references to standards in EU legislation is thus taking place *ex post*, leveraging an existing standard or technical specification, to provide guidance, or impose an obligation.

The practice of directly referencing standards in Union legislation is pervasive. As of December 2025, the Commission estimates **the number of unique references to standards in EU legislation[394] at around 3 500**[395].

2. STANDARDS FOR INDUSTRY USE

While standards developed under the Standardisation Regulation support a wide range of the EU *acquis*, **they only represent a small part of standards developed and used by industry**.

Standards are first and foremost private and voluntary documents, which are market-driven and adopted based on consensus, establishing common requirements for products, production processes, services or test methods to ensure interoperability, compatibility, safety and quality, as well as environmental and consumer protection where applicable. They play an essential role in creating economies of scale, facilitating exchanges between businesses by reducing technical barriers to trade and thus have an important impact on promoting the internal market, innovation and competitiveness. Standardisation in the industry builds on a long history: national standardisation bodies have been in operation since the beginning of the 20th century and the three ESOs, CEN, CENELEC and ETSI, were founded by stakeholders in 1961, 1973 and 1988 respectively, thereby preceding the creation of the internal market in their respective fields.

Many different organisations develop standards and technical specifications to support interoperability and trade. The TBT Agreement of the World Trade Organization (WTO)[396] aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade and requires the WTO TBT Committee to discuss specific trade concerns (STCs) related to specific laws, regulations or procedures that affect their trade. In 2000 the WTO TBT Committee defined six principles *"for the Development of International Standards, Guides and Recommendations*", with a view to guiding Members in developing standards supporting international trade[397]. These principles are now used as a benchmark to assess the ability of standardisation organisations to deliver standards with international relevance. The six principles for the standardisation process are:

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[394] This number does not include harmonised standards, the references to which have been published in the OJEU in compliance with Article 10 of Regulation (EU) No 1025/2012. However, this number may include references to harmonised standards which have been published in the OJEU outside of this framework.
[395] A large part of these directly referenced standards are ISO or IEC standards (more than a third).
[396] WTO, Agreement on Technical Barriers to Trade.
[397] 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 TBT Agreement.

transparency, openness, impartiality and consensus, effectiveness and relevance, coherence and taking into account the development dimension.

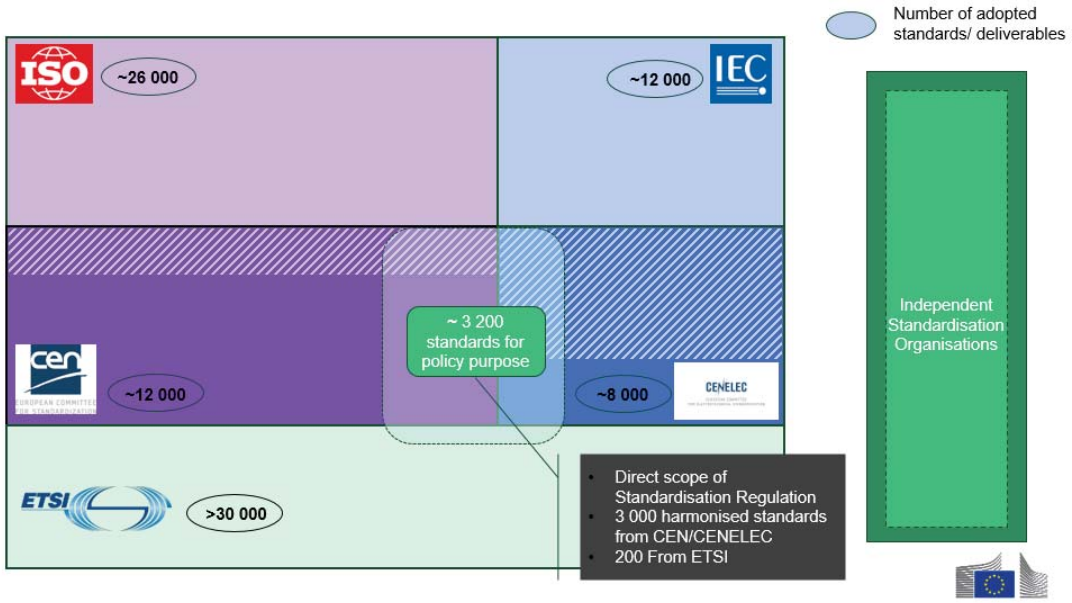
In turn, these principles were a source of inspiration for **the conditions set out in Annex II of the Standardisation Regulation** to identify ICT technical specifications from SDOs that are not ESOs which may be referenced by the Commission in public procurement, primarily to enable interoperability. Annex II states that such technical specifications have to be developed by a "*non-profit making organisation which is a professional society, industry or trade association or any other membership organisation*" with sufficient expertise and adopt specifications through a process that fulfils the openness, consensus, transparency requirements[398]. There is no European or international process that formally recognises SDOs that comply with the WTO TBT principles or with the principles from Annex II.

In general, the following types of organisations are involved in developing and adopting standards:

- **International standardisation bodies:** the International Standardisation Organisation, the International Electrotechnical Commission, and the International Telecommunication Union[399]:
- **National standardisation organisations:** most countries in the world host national standardisation organisations, which may be governmental or non-governmental organisations (ISO for instance gathers 195 organisations from 146 countries/territories).
- **Regional standardisation organisations**: these organisations gather national standardisation organisations from the same region such as CEN, CENELEC and ETSI[400] for Europe.
- **Independent standardisation organisations**, which abides by the WTO TBT principles mentioned above and that adopt standards in their area of expertise; these can be institutional sectoral organisations, such as the UPU for postal services or the Codex Alimentarius Commission for food, food production, food labelling and food safety, or independent organisation such as IEEE, ASTM, the World Wide Web Consortium (W3C) or 3GPP – see Annex 13 on alternative standardisation organisations.

Overview of harmonised standards within the standards ecosystem

[398] Annex II, paragraph 3 of the Standardisation Regulation. The Annex II also specifies requirements on the technical specifications themselves, in addition to the requirements on the organisation that developed them.
[399] As defined in Article 2(9) of the Standardisation Regulation. ITU status is however different from ISO and IEC as it is not an association of National Standardisation Organisation but an Agency of the United Nations.
[400] While National Standardisation Organisations are members of ETSI and ETSI adopts European Standards, it is also a membership-based standardisation organisation that adopt standards with international outreach.



3. SCOPE OF THE PROPOSED POLICY INTERVENTION

In line with the scope of the evaluation[401], the revision of the Standardisation Regulation targets **primarily the *ex ante* delivery of standards following Standardisation Requests from the Commission to the ESOs to support Union policy and legislation**, thus in practice concerns harmonised standards.

Thus, the initiative does not cover the direct references by the legislators of existing standards in Union law, as this concerns a legislative technique rather than the organisation the European Standardisation System to support Union legislation. Moreover, the current legal basis of the Standardisation Regulation (Article 114 TFUE) would not allow horizontal measures that address the practice of directly referencing standards in Union legislation.

The initiative does not cover the entire, privately-run standardisation system but only assesses the aspects relating to the delivery of standards for EU policy or legislative needs. However, the initiative, by targeting the *ex ante* delivery of standards in support of Union legislation and policy, has clear spill-over effects on the 2 dimensions mentioned above:

- As outlined in Annex 8, **the delivery of harmonised standards is an important activity of the European standardisation organisations**. Any changes in this process will have impacts on their functioning, both in terms of standardisation processes and financial revenues. While the Standardisation Regulation creates obligations for ESOs as regards harmonised standards, these obligations have repercussion on their development of industry-driven standards. Process improvements in the delivery of harmonised standards can spill-over on improvements in the delivery of standards by ESOs and make the entire standardisation system more competitive and more responsive to market and industry needs. By increasing the responsiveness of the European Standardisation System, the initiative can also contribute to increase the incentives of the industry to take part to standardisation activities, thus further

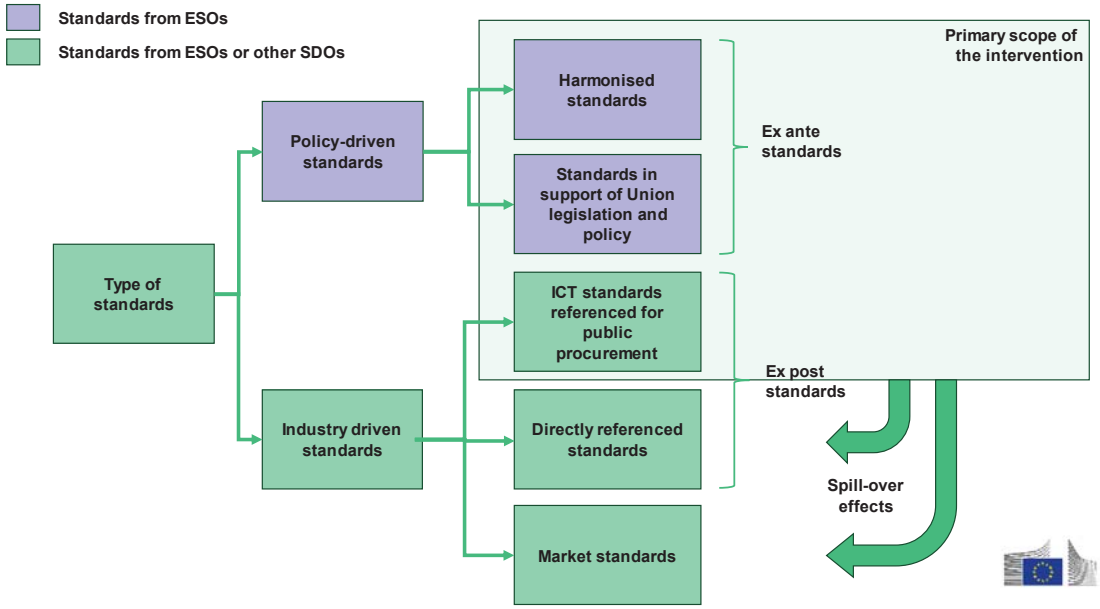
[401] Evaluation of the Standardisation Regulation, p. 5-8.

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reinforcing the contribution of standardisation to the internal market and the competitiveness of the EU.

- **Policy measures proposed for the revision of the Standardisation Regulation can also influence the direct referencing of standards** in Union legislation. In particular, the modalities to provide access to harmonised standards (see Annex 14) will influence the access granted to mandatory standards.

Overview of scope of policy intervention



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ANNEX 8: OVERVIEW OF THE FUNCTIONING OF THE EUROPEAN STANDARDISATION SYSTEM

1. THE EUROPEAN STANDARDISATION ORGANISATIONS (ESOS)

The Standardisation Regulation provides the legal basis for the European Standardisation System and establishes rules for the cooperation between European Standardisation Organisations, National Standardisation Bodies (NSBs)[402], Member States and the Commission for the establishment of European standards and European standardisation deliverables in support of Union legislation and policies.

The Commission can only request European standards to the three ESOs recognised in the Annex I of the Standardisation Regulation: the European Committee for Standardisation (**CEN**), the European Committee for Electrotechnical Standardisation (**CENELEC**) and the European Telecommunications Standards Institute (**ETSI**). Each ESO has its own specialised area of expertise: ETSI covers ICT and digital sectors, CENELEC focus on electrotechnical standardisation while CEN supports standardisation in a wide range of areas and sectors.

CEN, CENELEC and ETSI are private-law, non-for-profit entities with different governance, operation and financing models. CEN brings together the NSBs of 34 European countries, including all 27 Member States. CENELEC has the same organisation but for NSBs active in the electrotechnical field, the National Electrotechnical Committees. ETSI is an organisation based on direct membership, where any entity (public or private), which qualifies in terms of field of activity and expertise, can be a member; ETSI full members shall be established in one CEPT[403] country. It currently has over 900 members coming from 60 different countries. Most EU NSBs are members of ETSI, but do not have a privileged role in decision-making except when the decisions concern work requested by the Commission. Member States and EEA countries must notify their NSBs to the Commission, which lists them in the OJEU[404].

CEN, CENELEC and ETSI are standard development organisations but do not themselves draft the standards. Instead, it is the industry and their experts, research and societal experts and experts from public administrations that provide the expertise required to establish those standards, on the basis of different technical, legal and/or economic triggers from the market, and incur most of the associated costs – in particular, industry is estimated to bear around 90 % of the total standard development cost, mostly through their investments in mobilising their own experts[405]. The ESOs provide the infrastructures and administrative support necessary to the development of the standards and manage the development process to

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[402] National Standardisation Bodies are members of CEN, National Committees are members of CENELEC and National Standardisation Organisations from CEPT countries are members of ETSI, a subset of which National Standardisation Bodies from European Economic Area (EEA) – for ease of reference, the term NSB is used generally.

[403] European Conference of Postal and Telecommunications Administrations

[404] Publication of an update to the list of national standardisation bodies pursuant to Article 27 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council on European standardisation, OJ C 236, 4.7.2023, p. 3.

[405] Targeted interviews with the industry.

ensure quality and compliance with agreed upon standardisation development rules at European and international level[406].

CEN, CENELEC and ETSI are the only organisations to develop European standards[407] and other European standardisation deliverables, which have a harmonising effect on the internal market. NSBs must withdraw all national standards which conflict with adopted European standards, thus ensuring that there is one single and common standard used in the internal market. Harmonised standards are a specific type of European standards, adopted by ESOs following a request from the European Commission to support Union harmonisation legislation.

The large majority of CEN, CENELEC and ETSI's standardisation activities are initiated and carried out on their own initiative based on market needs, independently of requests from the Commission. Standards developed upon requests from the Commission represent between 17 % and 26 % of standardisation deliverables adopted by CEN and CENELEC since 2020[408]. For ETSI, the proportion of own-initiative standardisation deliverable is much higher, as harmonised standards represent less than 1 % of standardisation deliverables adopted by ETSI since 2020[409]. Overall, the contribution of CEN/CENELEC to the adoption of European Standards and harmonised standards is much larger than ETSI's – out of the 5 700 European Standards adopted by the ESOs since 2020, 97 % were from CEN/CENELEC. The importance of CEN/CENELEC for harmonised standards is similar (96 % of the 1 380 harmonised standards adopted).

CEN and CENELEC rely on the national delegation principle to develop and adopt standards. As the only members of CEN and CENELEC's, NSBs take all decisions on the development and adoption of CEN/CENELEC standards with each NSB reflecting in its vote the balance of the positions of all the interested parties in their country. NSBs manage the standardisation process at national level through national Technical Committees (TC), which feeds into the European level. They finance CEN and CENELEC through membership fees and in return have the exclusive right to sell the standards adopted by CEN and CENELEC, which is one of the main sources of financing of the ESS. Industry and stakeholders participating in the standardisation process are thus not financially compensated for the standards they develop; standardisation is an investment for them to have a seat at the table in shaping market trends that they recoup through easier market integration, interoperability and compliance with legal requirements when the standard is published in the OJEU. Contributors to standardisation may

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[406] Such as WTO "Technical Barriers to Trade (TBT) Agreement": WTO | Technical Barriers to Trade as well as provisions in EU free trade agreements.

[407] A European standard (EN) is a voluntary technical specification developed by CEN, CENELEC and ETSI, whereas a harmonised standard is a specific type of European standard developed at the request of the European Commission and, once cited in the Official Journal of the European Union, provides a presumption of conformity with relevant EU harmonisation legislation.

[408] The historical stock of harmonised standards in the total portfolio of CEN/CENELEC is however lower at 12 %. Recent years have shown an increase in the share of standards adopted upon request of the Commission in CEN/CENELEC activities.

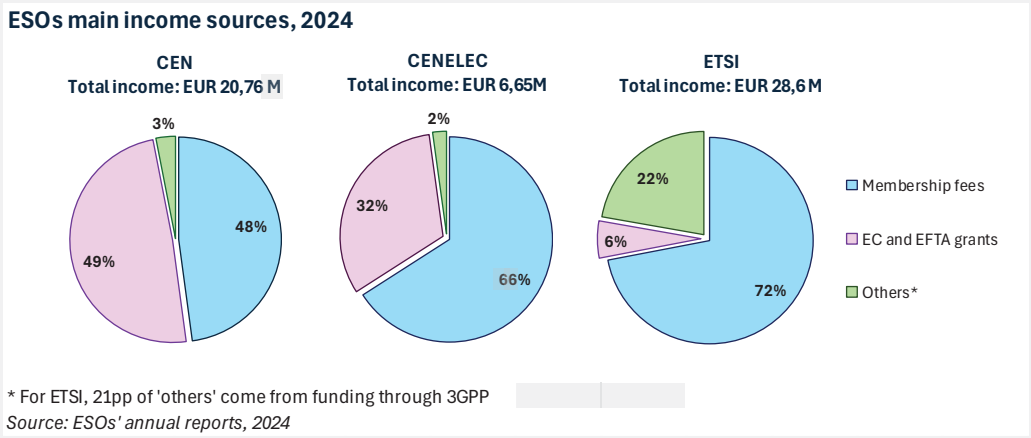
[409] However, harmonised standards represent 33 % of European standards adopted by ETSI since 2020; the large difference in this proportion is explained by large number of standardisation deliverables (technical specifications) that are not adopted as European Standards by ETSI – for instance, in 2025, ETSI adopted more than 3 000 standardisation deliverables, but only 41 (1.7 %) were European standards and 22 (0.7 %) harmonised standards.

also benefit from licensing patents including in their contributions, as well as for being early adopters of the standards, or for wide use of their technologies.

ETSI functions differently than CEN/CENELEC as a direct membership organisation. **ETSI does not sell its standards but makes them available for free on its website**. Its main revenue source is thus the membership fees paid by the actors willing to participate in ETSI's standardisation activities. One of ETSI's member categories are the National Standards Organisations (NSOs, 46 members from CEPT countries) that represent national interests in ETSI standardisation. The National Standardisation Bodies (NSBs) are the subset of the NSOs located in the European Economic Area (EEA). To fulfil their role as per Regulation (EU) No 2022/2480 (the amendment of Regulation (EU) No 1025/2012), a National Standardisation Bodies Group (NSBG) was established in 2023. The NSBG votes on the acceptance of Standardisation Requests by ETSI, the adoption/changes/stopping Work Items related to a Standardisation Request and the approval and withdrawal of standards and specifications related to a Standardisation Request.

The European Union also contributes to financing the European Standardisation Organisations. It covers part of CEN, CENELEC and ETSI's administrative and operational costs via operating grants through the Single Market Programme (SMP). It also finances projects of ESOs aimed at improving the standardisation process in the EU through dedicated action grants under the SMP, as well as projects to accelerate the development of standardisation deliverables in support of EU regulations and policies. The Union's contribution to the system represents a varying share of ESOs' total income, from around 6 % for ETSI to 30 % to 50 % for CENELEC and CEN – see Figure 8.1 for an overview of the financing structure of the 3 ESOs.

Figure 8.1: Estimates of ESOs' main revenue sources[410]



New revenue streams could include providing additional services on the standards, notably through the concept of "smart standards" to facilitate companies' understanding and use of the

[410] It is important to note that it is difficult to directly compare the revenues sources from ESOs due to their different business models. The membership fees received from ETSI directly finance the standardisation process. This is a different from CEN/CENELEC as the membership fees received come exclusively from NSBs in exchange from the exclusive rights to sell CEN/CENELEC standards.

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standards. Other possible revenue streams could include increase participation fees from the industry, moving closer to the current business model of ETSI relying on membership fees. This could however limit the participation of industries and stakeholders in the process. Last, financing could come from the public sector, in the form of increased compensation for the delivery of standards for policy purpose.

2. THE ESS BUSINESS MODEL

2.1. Organisation of the ESS

The ESS model relies on a public-private partnership at three main levels: (1) three ESOs, which have a (sectoral) monopoly at EU level, (2) a patchwork of NSBs at national level, with various business models, legal status and resources, and (3) industries, which are either member of NSBs (in the case of CEN and CENELEC) or directly ESO's members (in the case of ETSI).

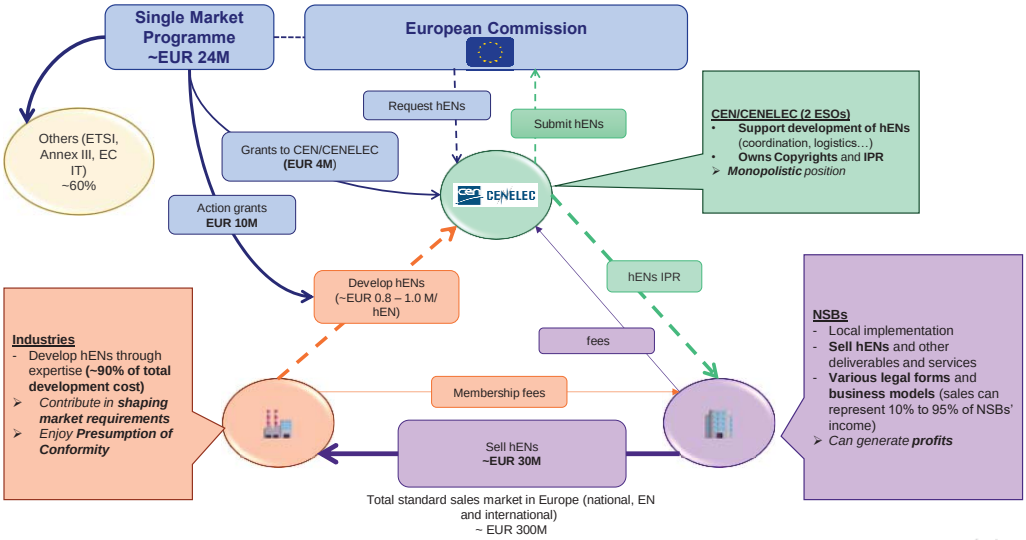
Within the ESS, standards are developed by industries with the support of ESOs and NSBs. Industry-mandated experts develop European standards (ENs) and harmonised standards, often in response to mandates issued by the Commission to ESOs, or market needs. Industries incur around 90 % of the total standard development cost. ESOs provide infrastructures and administrative support, while NSBs have voting rights on draft standards through their membership in ESOs' technical committees. As such, industries are not financially compensated for the standards they develop; they benefit from 'having a seat at the table' in shaping market requirements.

While industries effectively develop the standards, ESOs 'own' them and NSBs sell them[411]. CEN, CENELEC and ETSI claim ownership of copyright exploitation rights associated with the standards developed by industries. However, they do not sell the standards; instead, ETSI's standards are available for free and NSBs member of CEN/CENELEC act as the national distributors of European standards. They sell or license (i.e. access to a catalogue of standards) the standards to companies and other stakeholders within their respective countries. This relationship is illustrated in Figure 8.2.

Figure 8.2: Business model of CEN/CENELEC harmonised standards[412]

[411] In this case, this is limited to CEN and CENELEC.
[412] Commission own elaboration, based on the information gathered during NSB interviews carried out for the Impact Assessment Study and the NSB validation Workshop.

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2.2. Business model of ESOs

All three ESOs largely rely on membership fees to fund their activities. While the membership structure of CEN-CENELEC is composed of NSBs and National Committees (as well as other affiliates and partners) from 34 European countries, typically based on the country-specific indicators (e.g. GDP), ETSI's membership base is broader and includes companies (full members), research institutions and public authorities from over 60 countries – with fees varying depending on stakeholder type and company's size. Crucially, standards owned by ETSI are not sold, they are freely accessible[413].

The rest of ESO's resources come from public funding and services fees. The Single Market Program allocates around EUR 24 million each year to fund the ESS, for which the main part goes to ESOs[414] through operating and action grants – although most of these action grants are then transferred to industries providing experts work on the development of standards. While CEN and CENELEC depends on EU grants for respectively half and one-third of their revenue, ETSI is more 'independent'. Another particular aspect of ETSI' revenues is the funding it receives from its role of global secretariat for 3GPP[415].

[413] ETSI's standard may rely on technology under IPR protection from private companies. In those cases, ETSI standards clearly indicate the IPR protection on the standards, and the companies contributing with patented technology commit to license their IPRs for the use of the said standard under fair, reasonable and non-discriminatory (FRAND) terms.

[414] But not only. For instance, it also serves as funding Annex III organisations

[415] ETSI acts as the global Secretariat (Mobile Competence Centre) for the '3rd Generation Partnership Project' – a global collaboration project on mobile networks (3G, 4G, 5G and the upcoming 6G). Other members include ATIS (US), CCSA (China), ARIB&TTC (Japan), TTA (South Korea) and TSDSI (India), which pay a contribution to ETSI for its Secretariat role.

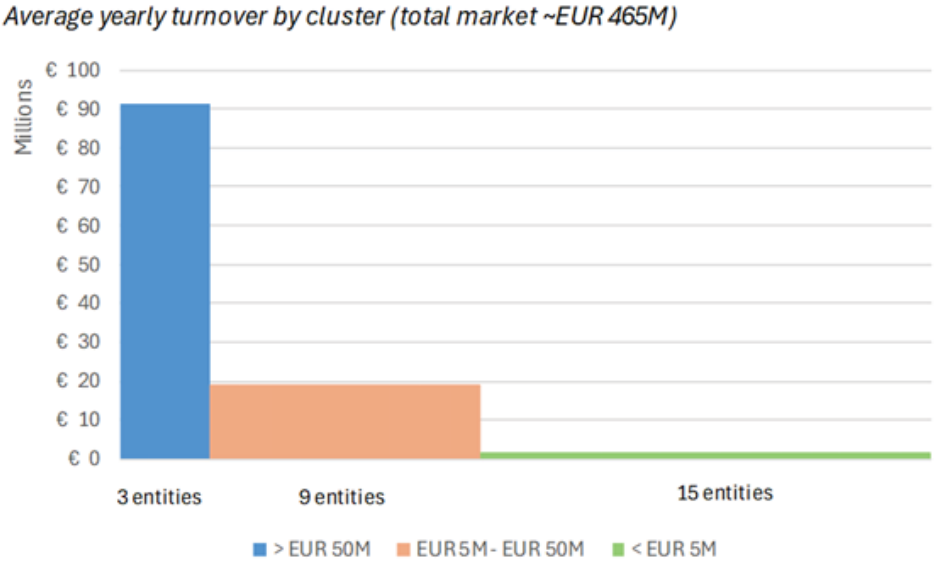
2.3. Business of models of NSBs

National Standardisation Bodies present various legal forms. The two main legal forms identified are private non-profit associations, most common form observed in Western and Northern Europe, and public entities, prevalent in Central and Eastern Europe[416].

The business models are even more diverse than their legal form. While there is little public data, and no harmonisation or established benchmark to compare them with, the annual report on NSBs' website allow to identify certain trends: revenue generated by each NSB varies widely, as does the scope of their activities. In fact, certain NSBs are focused on standardisation activities while for others, standardisation only represent a share, sometime minor, of the services they offer and income they generate.

The variety of legal forms and business models makes it hard to compare and draw conclusions, but certain trends can be identified. As such, the ESS is largely dominated by three main players (see Figure 8.3)[417]. Rather than the size of the nation's internal market, the defining factors influencing revenue generation seem to be the legal form and the variety of services offered. As such, private non-for-profit entities and those offering more services generate a higher turnover than public ones and those focused on standardisation only. Importantly, NSBs with diversified activities capitalise on their "NSB status": by becoming the national reference point on standardisation, NSBs can use this position to offer and advertise additional, more profitable services, such as training or certification.

Figure 8.3: EU standards' market breakdown by cluster of NSBs



Source: data shared by NSBs (27/34), consolidated

[416] Only Latvia's LVS is a private limited company.
[417] For the purpose of this note, the ESS is limited to EU's NSBs. BIS, the British NSB (also member of the ESS) is otherwise by far the largest NSB in Europe – with above £ 700 million revenue per year.

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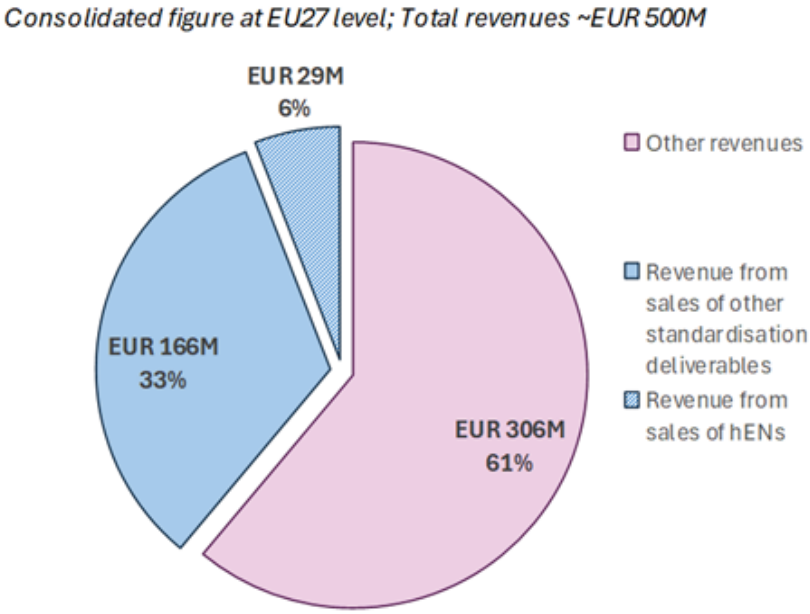
2.4. NSBs' exposure to the sale of (harmonised) standards

Providing free access may challenge the business models which NSBs rely on. Standards, including harmonised standards and those referenced in EU legislation, are sold by NSBs. As the judgments of the CJEU clarified that standards that have a legal effect should be freely accessible, this business model is being challenged, potentially threatening the financial stability of some NSBs, as well as ESO's interest and ability to accept standardisation request from the Commission and deliver standards that they could not be able to monetise.

Individual exposure varies widely across NSBs, depending on their dependence on the sale of standards in their total revenues and their capacity to diversify the services they offer. In a nutshell, smaller NSBs are more exposed, as they derive most of their revenues from standardisation activities and notably the sale of standards. However, even among the larger NSBs, exposure can also be high. Figures 4 and 5 below show the individual exposure of 27 NSBs to sales of European standards and of harmonised standards.

The consolidated value shows a limited exposure of NSBs to the sales of harmonised standards: 6 % of total revenues and 15 % of revenues from sales of standards alone – Figure 8.4.

Figure 8.4 – Breakdown of NSBs' revenues by activity

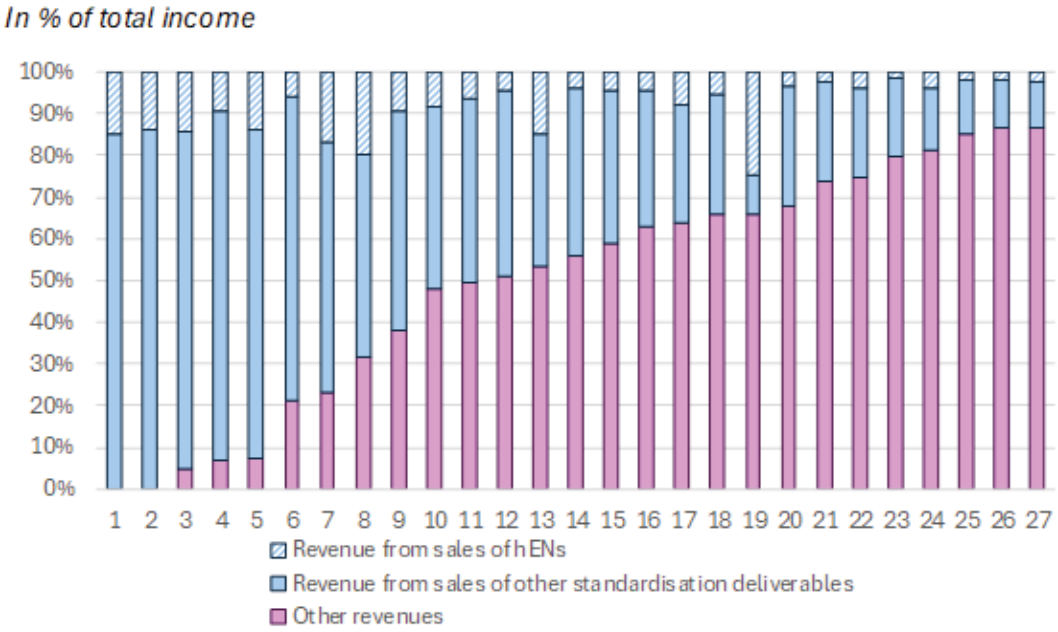


Source: 27/34 NSBs/NCs shared data; 6/34 figures estimated by CCMC

However, there is a wide disparity across NSBs: exposure to sales of all standards in total revenues vary from 13 % to 100 % - see Figure 8.5.

Figure 8.5: Exposure to sales of standards by NSB

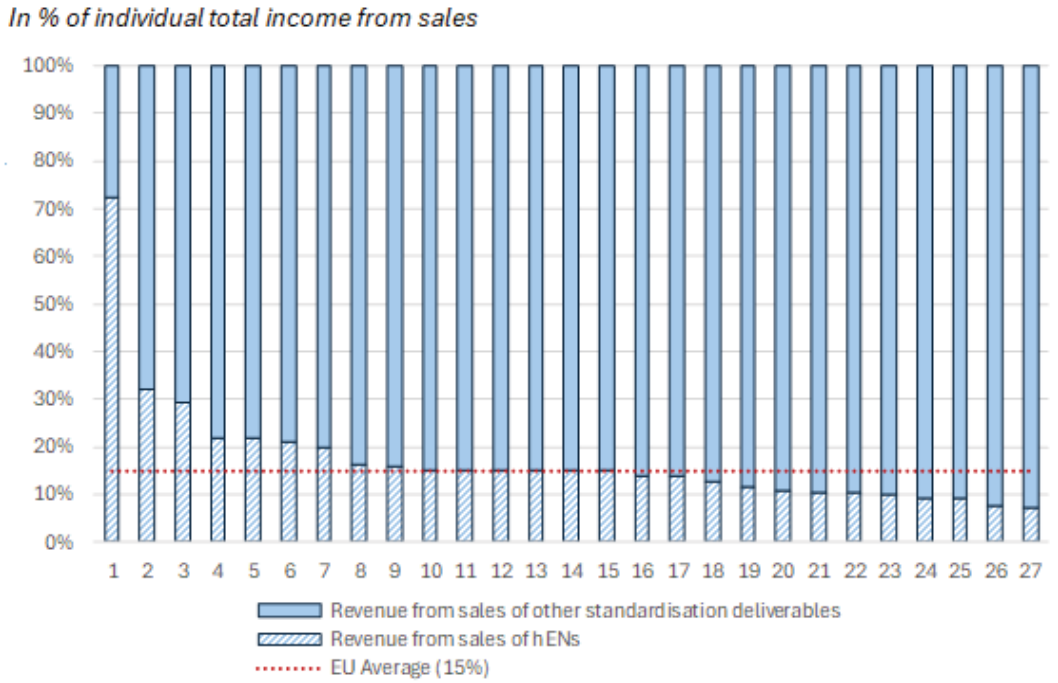
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Source: data shared by NSBs

Looking at the share of hENs in the sales of all standards, there is also discrepancies across NSBs, with exposure ranging from 7 % to 32 %, with one NSB standing out with a 72 % exposure – see Figure 8.6.

Figure 8.6: Exposure to sales of hENs (over total sales of standards) by NSB



Source: data shared by NSBs

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The total consolidated sales of hENs in the EU are thus estimated at about EUR 30 million per year, representing on average 15 % of NSB's sales of standards (in value) – with varying individual exposures.

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ANNEX 9: KEY ELEMENTS AND FUNCTIONING OF THE STANDARDISATION PROCESS IN REGULATION (EU) 1025/2012

Regulation (EU) No 1025/2012 establishes rules with regard to the cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation and the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies.

This involves setting out the mandate for the European standardisation organisations by the Commission, drafting European standards and standardisation deliverables by the European standardisation organisations and the assessment of the result by the Commission and the European standardisation organisations. During this process, several factors contribute to the 6 years on average required to develop a standard and publish its reference in the Official Journal of the European Union (OJEU).

1. KEY ELEMENTS OF REGULATION (EU) 1025/2012

A **harmonised standard** is a European standard adopted by one or more European standardisation organisations (ESOs), following a request from the European Commission, in order to support Union harmonisation legislation. Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in relevant Union harmonisation legislation, its references must be published in the OJEU by the Commission, or by other means (like e.g. addition to an Annex via secondary legislation) in accordance with the conditions laid down in the corresponding legal act. A **European standard** is a standard adopted by one or more of the European standardisation organisations.

The **Annual Union Work Programme** (AUWP) for European standardisation outlines priority areas and objectives that identify potential initiatives to align with standardisation efforts. The AUWP is developed by the Commission in cooperation with the ESOs, EU Member States, and other stakeholders, including the High-Level Forum on Standards (HLF). It also serves as a notice to stakeholders and the public about what to expect in the field of European standardisation for the upcoming year, as the Regulation mandates publication of the AUWP.

The Regulation lays down requirements for the ESOs in order to ensure a wide range of **stakeholder participation** in the standardisation process, in particular when ESOs draft harmonised standards which will form 'part of EU law'. The regulation also imposes obligations on NSBs to facilitate the participation of SMEs in standardisation activities and facilitate access to standards for SMEs, not necessarily for other stakeholder groups. The objective is to lower barriers for SMEs to participate, as standardisation is a costly and time-consuming process. This ensures that the standards reflect a broad set of interests and minimises any negative impact on the stakeholder groups.

The activities governed by this Regulation are the following:

- Activities to enhance **transparency** (Articles 3 to 4), whereby the ESOs and NSBs are required to (i) publish work programmes to enhance transparency between NSBs and (ii) provide access to standards, including access to draft versions of standards at the request of the Commission, so that relevant stakeholders can input if need be.

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- Activities to enhance **stakeholder participation** and inclusion (Articles 5 to 7), as the ESOs are required to encourage and facilitate access (i) to all relevant stakeholders, including SMEs and workers' organisations, as well as environmental and social stakeholders, in all standardisation activities, as well as (ii) to research centres, universities and other legal entities, in standardisation activities concerning an emerging area with significant policy or technical innovation implications under the multi-annual framework programmes under Article 182 TFEU. NSBs are required to encourage and facilitate the access of SMEs to standards and standard development processes, by implementing specific tasks (Article 6 (1)). Furthermore, they are required to (i) exchange best practices on how to enhance SMEs participation (Article 6 (2)) and (ii) send annual reports to ESOs with regard to the activities implemented to favour the involvement of SMEs. Member States are required to encourage participation of public authorities, including market surveillance authorities, in national standardisation activities.
- Activities to **support Union legislation and policies** (Articles 8 to 12) includes an obligation for the Commission to publish an Annual Union Work Programme on European standardisation, as well as a detailed procedure of how the European Commission requests standards to the European standardisation organisations, including the roles and responsibilities of the ESOs and the Commission in checking the compliance of standards with EU legislation before the Commission decides to publish their reference in the OJEU. As a safeguard, Member States and the European Parliament have the possibility to initiate formal objection procedures in case they ascertain non-compliance of harmonised standards with Union harmonisation legislation.
- Activities to support the **identification of ICT technical specifications** (Articles 13 and 14) for use in public procurement and in support of the European multi-stakeholder platform on ICT standardisation.
- Activities to **finance European standardisation** (Articles 15 to 18), based on grants the EU budget finances the ESOs and European stakeholders (so-called 'Annex III organisations') that meet the criteria set out in Annex III of the Regulation. The ESOs and Annex III organisations are required to provide an annual implementation report to the Commission. Similarly, the Commission is required to provide multi-annual implementation reports to the European Parliament and the Council (Article 24).

2. DEVELOPING HARMONISED STANDARDS

Findings of the evaluation show that the **initial phase of the development of a standard** (Phase A, policy phase), covering the adoption and notification of standardisation request by the Commission, which includes consultations with ESOs, Member States and stakeholders, **takes on average 1.7 years**, an actual increase compared to pre-Regulation (9 months in 2012), but also compared to 2014 (1.5 year). The **second phase** (Phase B, delivery phase), covering the acceptance of standardisation request and the drafting stage (usually comprising the consensus-building process), **accounts for more than three years** – a relative decrease compared to the period before the Regulation was in place but highly fluctuant. The **last phase** (Phase C, publication phase), encompassing submission by ESOs to the Commission, and the publication in the OJEU, covering the compliance assessment by the Commission services, **takes on average 14 months** – the most substantial improvement since the Regulation is in place (it took on average 5.4 years before 2012).

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2.1. Phase A: policy phase

1. **Strategic Planning and the Annual Union Work Programme (AUWP)**: the European Commission, in consultation with stakeholders, identifies strategic priorities for European standardisation and outlines these in the Annual Union Work Programme. The AUWP is developed by the Commission in cooperation with the ESOs, EU Member States and other stakeholders, including the High-Level Forum on Standards (HLF). It also serves as a notice to stakeholders and the public about what to expect in the field of European standardisation for the coming year.
2. **Request from the European Commission**: based on the priorities set out in the AUWP, the Commission issues standardisation requests to the ESOs to develop harmonised standards.
3. **Acceptance of the Request**: the relevant ESO (or ESOs) evaluates and may accept or reject the request. If it accepts the requests, the ESO commits to developing the standard within the timeframe set out in the request.

A first factor driving the long adoption time for Standardisation Requests relates to procedural requirements. Standardisation requests are increasingly detailed and specific as regards the requirements for standardisation deliverables, in particular since the new template was adopted in 2019[418]. As a consequence, preparing standardisation requests increasingly requires technical expertise and the anticipation of the structure and characteristics of the standardisation deliverables request, in particular for harmonised standards. Moreover, the Standardisation Regulation requires the positive opinion of the Committee of Standards, in which Member States are represented, for each standardisation request. In recent years, this step has become a formality, as all Standardisation Requests have received a positive vote, with the exception of 2 case in which vote was taken[419]. Nonetheless this step adds between 2 and 6 months to phase A, due to the time necessary to allow for informing the Committee and the subsequent vote[420].

A second factor responsible for the adoption time of standardisation requests is the consultation of stakeholders, in particular ESOs. While these consultations are necessary and improve the quality of the requests, in view of their increased complexity, they can also lead to long delays in their adoption, notably when there is disagreement between the Commission and the ESOs. In the case of Cybersecurity Standards for Radio it lasted over five years counting from the initial discussions to the acceptance of the standardisation request by CEN and CENELEC (June 2017 to September 2022). While the consultation phase ensures a

[418] Following the judgment in case C-613/14 *James Elliott Construction*.
[419] Draft standardisation request as regards structural metallic products, ancillaries and double skin metal faced insulating panels (August 2025) and draft standardisation request on climate services standards (March 2026, reference not yet available). The total number of Standardisation Requests submitted to the Committee vote over the period is 60.
[420] The Evaluation Study shows that the comitology procedure on average takes 50 days, but this does not include the pre-consultation of the Committee of Standards.

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high acceptance rate of Standardisation Requests by the ESOs, since only 3 requests were rejected in the past 5 years[421], it also contributes to delays the overall standardisation process.

Finally, the adoption of standardisation requests can be delayed by a lack of anticipation and planning that would allow to align interests of the Commission and the ESOs before engaging in their preparation. The Evaluation highlighted the difficulties of the ESOs to engage stakeholders on important topics in the future, despite those noted as priorities in the AUWP[422]**.** For instance, in the case of hydrogen infrastructure, or low-carbon cement, digital product passport (DPP). The High-level Forum on European Standardisation (HLF) was set up, notably to address this issue, and to help stakeholders – Member States, ESOs, the industry and Annex III organisations – coordinate to anticipate standardisation needs. For instance, the HLF set up dedicated workstreams on the priorities mentioned above – low carbon cement, digital product passport (DPP), hydrogen, to speed up the preparation of the stakeholders for standardisation. In the case of the Artificial Intelligence Act, the Commission held regular meetings with the ESOs before adopting the Standardisation Request in order to anticipate planning of the activities and aid in mobilising the needed experts. In the digital field, the ICT standardisation Rolling Plan lists the standardisation needs to support EU regulation and policies, allowing anticipation of ESOs' planning. Overall, the slow responsiveness of the ESS to the standardisation priorities set out in the AUWP contributes to extending the duration of standard development processes. This is in particular the case in new standardisation areas where the adoption of requests can be delayed due to the lack of relevant experts or technical committees available to deliver the harmonised standards, or to uncertainty as to which ESO would be best placed to work on the standards.

2.2.Phase B: delivery phase

This phase is not explicitly defined in the regulation as it mainly concerns the internal procedures of the ESOs.

4. **Work Programme and Development**: the work item is included in the ESO's work programme. The ESO assigns it to a technical committee or body with the relevant expertise. This committee is responsible for preparation and drafting the standard. It involves a consensus-driven process that includes input from various stakeholders, such as industry representatives, consumer groups, SMEs, and public authorities, including the European Commission.
5. **Public Inquiry and Commenting**: a draft standard is made available for public inquiry and comments. This is an important step for transparency and inclusiveness.
6. **Review and Approval**: comments are reviewed, the draft may be revised, and the standard is submitted for formal voting by ESO members, which are the national standardisation bodies.
7. **Adoption and Publication:** following a positive vote, the standard is adopted as a European standard (EN) and published by the ESO(s). Subsequently, the NSBs must adopt

[421] The rejections were due to disagreement by the ESOs on the technical content of the requested standards and/or on the deadlines for the adoption of the standards inserted in the requests.
[422] Evaluation of the Standardisation Regulation, p. 39.

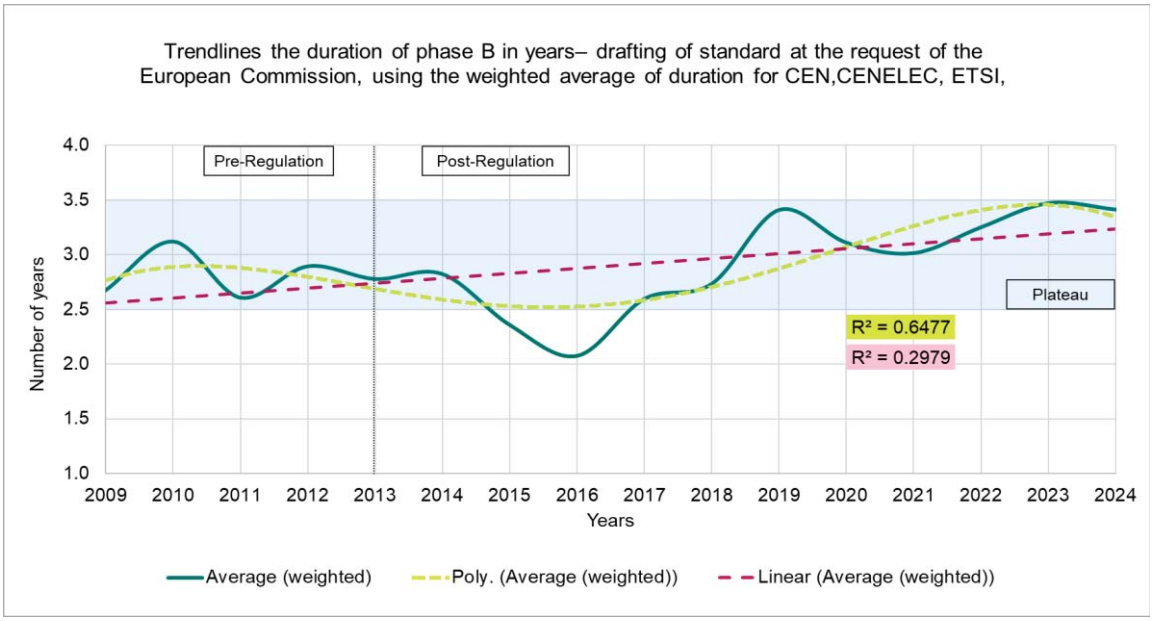
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the harmonised standard as a national standard and withdraw any conflicting national standards.

8. **Notification to the European Commission**: the ESO notifies the Commission and provides the reference of the harmonised standard.

The average duration of this process is 3 years, but varies significantly across standards and sectors, and an upward trend is visible – see Figure 9.1.

Figure 9.1: Evolution of average time to deliver a standard by ESOs[423]



Here, there is a **need to reach consensus and to ensure effective collaboration and discussion among industry stakeholders and with societal stakeholders** to agree on technical solutions that both mirror their interests and the legislative requirements. Delays often occur because, in some cases, industry may have limited incentive to participate in developing standards with societal dimension of for public interest that might cause higher costs than benefits for their businesses as for instance happened in the case of the common charger.

Moreover, delays may occur due to the lack of availability of relevant industry experts that can be mobilised by the ESOs. In certain cases, sector-specific organisations may possess the right expertise to develop timely and high-quality standards but are not eligible to receive standardisation requests from the European Commission under the current legal framework. For instance, in the case of standards for drones, ESOs encountered difficulties to mobilise experts from their constituency while specialised organisations such as EUROCAE could have developed industrial standards more efficiently[424].

The issue of lack of expertise is broader as the delivery of harmonised standards requires a combination of expertise on technical matters and legal matters to ensure that the proposed

[423] Impact assessment study, p. 10.
[424] Targeted interviews.

standards adequately meet the essential requirement set in the legislation. The absence of systematic internal quality controls within the ESOs on the legal aspects generates delays and increases the likelihood that (draft) harmonised standards might receive a negative assessment from the Commission services, delaying the drafting process further.

Lack of expertise and insufficient participation of relevant experts in the standardisation process is particularly acute in new technologies where the shortage of European experts is linked to the nascent nature of the industry, to the lack of European industries in some parts of the value chain, as well as the prioritisation of the industry on other activities, such as research and innovation[425].

2.3.Phase C: publication phase

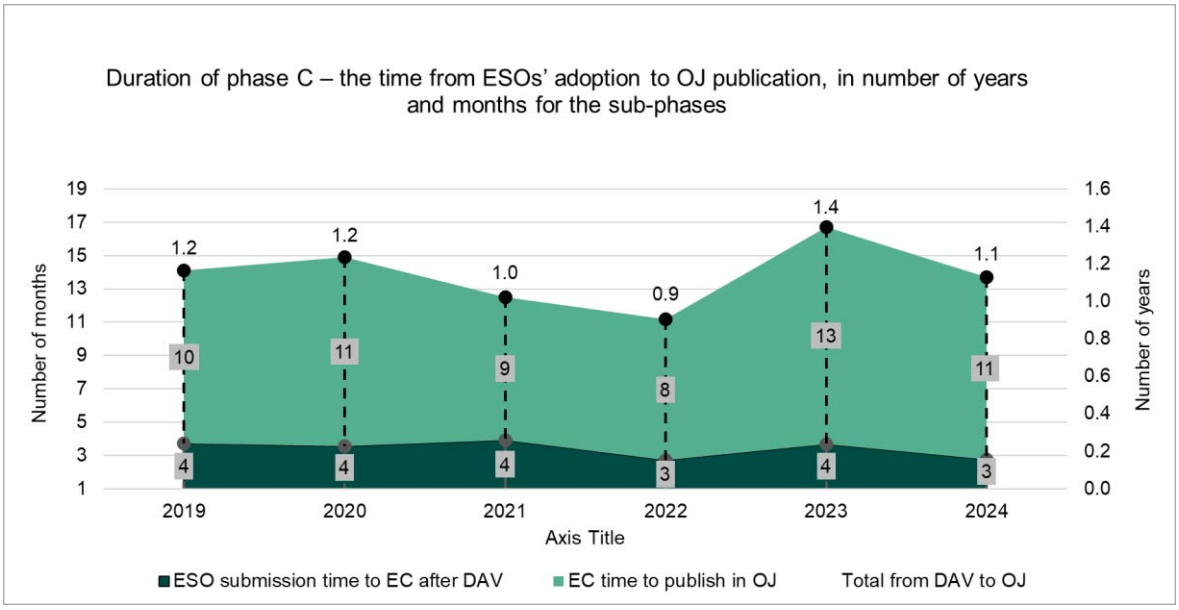
9. **Notification to the European Commission:** the ESO notifies the Commission and provides the reference of the harmonised standard.
10. **Publication in the Official Journal of the EU:** the Commission must assess the compliance of each adopted harmonised standard to determine whether it covers the essential requirements set out in the request. If it meets the requirements, the Commission must publish its reference in the Official Journal (to provide a presumption of conformity or other legal effect depending on the EU legislation concerned).
11. **Maintenance:** standards are living documents and may need to be updated, amended or withdrawn over time to reflect technical innovation, changes in regulation, or other factors.

Phase C lasts between 1 and 1.4 years – see Figure 9.2 – and **is considered lengthy, in particular from the viewpoint of stakeholders and ESOs, as the harmonised standard is ready to be used**, having been adopted by the ESO (Date of availability (DAV)) representing the "state of the art" but the Commission first needs to assess the standards. One of the main causes of the time required here pertains to quality.

Figure 9.2: Duration of the publication phase (phase C)[426]

[425] Impact assessment study, p. 11.
[426] *Ibid*, p.11.

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DAV: Date of Availability, meaning the moment when the final text of the standard is made available and sent by CEN and CENELEC to their national members (the NSBs), for transposition at national level.

Besides issues regarding the quality of the offered standards, **procedural and organisational issues add time to this phase of the process**. Whereas until 2017, the references to standards were published in the C-series of the OJEU in the form of a Commission Communication, today the references are published in the L-series of the OJEU[427] following a Commission Implementing Decision – a legally binding act – in the sense of Article 291 of the Treaty on the Functioning of the EU, which requires an adoption process by the College as well as translation EU official languages. More importantly, due to constraints on resources and expertise, the Commission has outsourced a large part of the assessment of harmonised standards to external consultants[428] that are tasked with the technical analysis of assessing whether the standard complies with the essential requirements and the standardisation request. Coordination issues between the Commission, HAS consultants and the ESOs are frequent reasons for delays in the assessment[429].

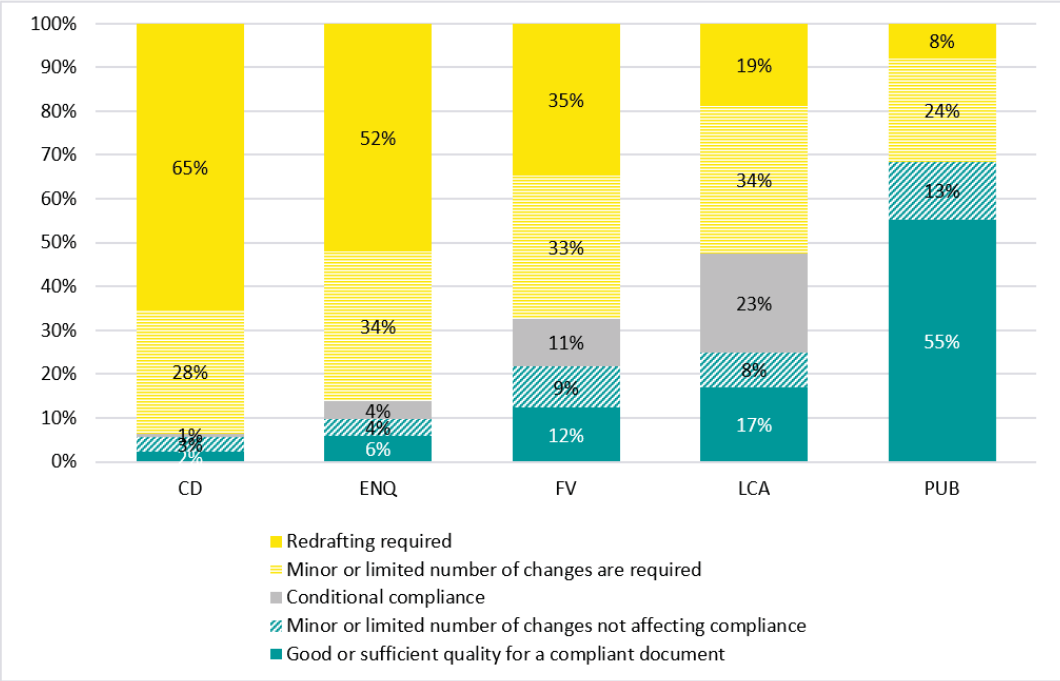
Another root cause of delays is **the frequent misalignment of standards delivered by ESOs with the legal requirements** laid down in EU legislation as set out in the standardisation requests, leading to high rejection rates (65 % at first review, 32 % at publication). These compliance failures trigger repeated revision cycles, additional scrutiny, and prolonged discussions between the Commission, HAS, experts, and ESOs. A deep dive conducted for the Evaluation on 525 standards rejected between 2016 and 2024 found 38 % were rejected for non-eligibility[430], mostly due to a misalignment with the supported legislation, and 62 % for

[427] Following the judgment in C-613/14 *James Elliott Construction*.
[428] The HAS consultants for most NLF legislation, and another system of consultants for Ecodesign legislation.
[429] Impact assessment study, p. 11.
[430] Non-eligibility notably includes the cases when legislation supported by the standard had been repealed (58 % of the cases) or cases when the standard did not support the legislation under which it was proposed (26 %). Impact assessment study, p. 12.

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non-compliance (46 % for both formal and substantial reasons[431], 32 % for formal only and 22 % only for substantial[432]) – see Figure 9.3.

Figure 9.3: Assessment of standards by HAS consultants by phase of development[433]



Contributing to these failures are **differing interpretations of essential requirements, insufficient legal guidance during drafting, ESO internal procedures that hinder late revisions, and technical experts' difficulties with hEN formal requirements**[434]**.** A November 2024 workshop[435] revealed that 71 % of respondents cited poor Commission-HAS-ESO communication as a key delay factor, while 40 % pointed to the increasing pace of legislation. The frequently long formal objection procedure, whereby Member States can challenge the compliance of hENs with essential requirements after they have been referenced, also add to the uncertainty on the quality and validity of hEN[436].

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[431] Formal reasons mainly concern issues related to the drafting of Annex Z (which regroups the legally relevant content of the hEN) and the inclusion of undated normative references. Substantive reasons generally involve conflicts between the content of the standards and legislative requirements, as well as the use of non-verifiable or non-repeatable requirements.

[432] Evaluation Study, p.66.

[433] Analysis based on 1 616 assessments conducted by HAS consultants between August 2024 and November 2025. CD: Committee Draft, ENQ: Enquiry stage, FV: Formal vote, LCA: Last Confirmatory Assessment and PUB: publication stage.

[434] Impact assessment study, p. 12.

[435] Validation workshop gathering 220 participants from 21 Member States, held online on 6 November 2024, presenting the preliminary findings of the evaluation study of the Standardisation Regulation to stakeholders.

[436] Evaluation, p. 27 and 35. Between 2014 and 2024, Member States filed 41 formal objections, 22 % of which led to restrictions (hence a limitation of the scope of applicability of the hEN). The mechanism functions slowly requiring on average 21 months before certainty on the hEN is provided to stakeholders.

3. DEVELOPING COMMON SPECIFICATIONS

While not covered by the Standardisation Regulation, several pieces of sectoral Union legislation provide for the possibility to adopt common specifications[437].

The Omnibus IV legislative proposal introduces the possibility for the Commission to further adopt common specifications as a fall-back option to harmonised standards in an additional 16 regulations and directives[438]. Some legal acts that rely on harmonised standards do not provide for the option to establish common specifications[439].

The Commission can adopt common specifications as a fall-back to harmonised standards when they are not available. Common specifications can grant presumption of conformity to undertakings complying with them, as would harmonised standard. While each sectoral legislation can have its specific conditions and process to adopt common specifications, the Commission can generally adopt them only when the standardisation process has failed, either because ESOs have not accepted the standardisation request, are late in the delivery of the harmonised standard or have offered a harmonised standards that does not adequately translate the essential requirements it aims to cover.

Common specifications do not generally increase the speed of standardisation nor contribute to anticipate when market operators can benefit from presumption of conformity. The Commission can usually prepare common specifications only when the ESOs are late or fail to deliver a hEN, so once the standardisation process is already well advanced, and generally close to the date of applicability of the legislation they are supporting. Second, common specifications have until now very rarely been used as a policy tool. In recent years, the Commission only adopted common specifications in the framework of the Medical Device and

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[437] Directive (EU) 2016/797 (on the interoperability of the rail system), Directive (EU) 2016/2102 (Web Accessibility Directive), Directive (EU) 2016/1629 (on technical requirements for inland waterway vessels), Regulation (EU) 2017/745 (on Medical Devices), Regulation (EU) 2017/746 (on In Vitro Diagnostic Medical Devices), Directive (EU) 2019/882 (European Accessibility Act), Regulation (EU) 2019/1009 (Fertilisers Regulation), Regulation (EU) 2023/1230 (Machinery Regulation), Regulation (EU) 2023/1542 (on batteries and waste batteries), Regulation (EU) 2024/1689 (AI Act), Regulation (EU) 2024/1781 (Ecodesign for Sustainable Products), Regulation (EU) 2024/2748 (emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency), Regulation (EU) 2024/2847 (Cyber Resilience Act), Regulation 2025/2509 (Toy Safety Regulation), Regulation (EU) 2025/327 (European Health Data Space), Regulation (EU) 2024/3110 (Construction Products), Regulation (EU) 2023/2854 (Data Act). The Commission's Proposal for a Space Act (COM(2025)335 final) also foresees the possibility of adopting Common Specifications

[438] Directives that are modified by the Omnibus IV proposals are: Noise emission in the environment by equipment for use outdoors - Directive 2000/14/EC, Recreational craft and personal watercraft - Directive 2013/53/EU, Simple Pressure Vessels - Directive 2014/29/EU, Electromagnetic Compatibility - Directive 2014/30/EU, Non-automatic Weighing Instruments - Directive 2014/31/EU, Measuring Instruments - Directive 2014/32/EU, Lifts - Directive 2014/33/EU, ATEX - Directive 2014/34/EU, Low Voltage - Directive 2014/35/EU, Radio equipment - Directive 2014/53/EU, Pressure equipment - Directive 2014/68/EU, Marine Equipment - Directive 2014/90/EU, Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU.
Regulations that are modified by the Omnibus IV proposals are: Cableway installations - Regulation (EU) 2016/424, Gas appliances - Regulation (EU) 2016/426, Personal protective equipment - Regulation (EU) 2016/425 , Requirements for accreditation and market surveillance relating to the marketing of products - Regulation (EU) 2008/765.

[439] Regulations (EU) 1907/2006, (EU) 1223/2009, (EU) 2019/945, (EU) 2019/2014 and (EU) 2023/988 and Directives 97/67/EC, 2009/128/EC, 2011/65/EU, 2013/29/EU, 2014/28/EU and (EU) 2019/904.

In Vitro Medical Device Directives[440]. The common specifications were adopted after a period of 3 to 5 years, showing that the drafting time is not shortened compared to hEN. They were available either on time for the In Vitro Regulation or with 18 months delay for the Medical Device Regulation. In these two specific cases, the legislation did not include the requirement for the Commission to leverage first the standardisation system to obtain a hEN before adopting the common specifications, but only the requirement that there was no existing relevant hEN, which allowed the Commission to start the drafting process much earlier than if it had to request a harmonised standards to the ESOs first.

4. SUPPORT TO INCLUSIVENESS OF THE ESS UNDER THE STANDARDISATION REGULATION

4.1. SMEs and civil society representation and participation

Article 5 of the Regulation requires ESOs to "*encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including **SMEs, consumer organisations and environmental and social stakeholders** in their standardisation activities"*. To support this objective, the Union finances the participation of European stakeholder organisations listed in **Annex III of the Regulation**.

At CEN and CENELEC, participation by Annex III organisations in technical discussions, including technical committees, sub-committees, working groups and other miscellaneous groups, has increased over time. At ETSI, the number of representatives increased for all Annex III organisations (except for ANEC which has remained at the same level), although no figures on the effective participation are reported. To increase the visibility of societal stakeholders and SMEs in standardisation, ETSI also launched the "3SI programme", including the nomination of an advocate for societal and SME interests.

However, targeted interviews with Annex III organisations reveal that participation is not always perceived as leading to real effects. Beyond participation, Annex III organisations can formally vote in ETSI in the same way as all other members, while in CEN and CENELEC they can express formal opinions. CEN reports an increasing number of opinions, with a growing share of non-favourable opinions received in the last three years (16% in 2020, 39% in 2022). The number of opinions received by CENELEC is overall more stable. Participation of societal stakeholders at national level (as a percentage of NSBs in which societal interests are represented) varies between 47% and 77%, in 2025. While 67% of respondents to the OPC (401 out of 599) consider the national level as the most inclusive, targeted interviews with Annex III organisations, public authorities and national societal organisations suggest that national societal organisations are not adequately represented in NSBs.

Representation and direct participation by SMEs in both national and European technical committees is recognised as crucial for the functioning of the ESS (Recital 20 of the

[440] Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices for the In Vitro Medical Device Regulation and Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

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Regulation). **Article 6 of the Regulation** requires NSBs to encourage access of SMEs to the standards development process.

In reality, their involvement varies, with 31 out of 34 in CEN-CENELEC's NSBs and 26 out of 39 in ETSI's NSOs involving SMEs. Financial support for SME participation in standardisation varies widely across Member States. The Commission provides annual subsidy to an organisation representing SMEs interest in standardisation. 77 % of NSBs liaise with stakeholder groups to recruit SME representatives for technical committees and working groups. 22 % of ETSI's membership is made up of SMEs. Targeted interviews with companies and industry associations show that the representation of SMEs has improved under the Regulation, yet barriers remain, notably a lack of resources for SMEs and startups to participate effectively and a lack of expertise in standards development.

4.2. The articulation between standardisation and research and innovation (R&I)

Standardisation is an important valorisation channel for research results to turn into innovative products and services which can be scaled on the market and gain consumers' trust. To ensure that research results can be translated into standardisation deliverables, and that standards can accelerate innovation and support timely market uptake, it is important to rely on **a consistent mechanism for supporting the link between research and R&I actors and standardisation**, especially if publicly funded. The EU framework programmes, in particular **Horizon Europe**, can play a key role in supporting standardisation through pre-normative research, expert mobilisation and the integration of standardisation activities in project design to increase awareness of the processes involved.

Article 5 of the Standardisation Regulation introduced requirements for ESOs to encourage and facilitate the appropriate representation, at technical level, of research and innovation actors funded under a multiannual framework programme for activities in the area of research, innovation and technological development. CEN, CENELEC and ETSI have introduced various workstreams to foster cooperation with universities and researchers[441].

The articulation of the standardisation and R&I communities is also essential to ensure a timely identification of future standardisation needs, which is implemented through the Annual Union Work Programme on European Standardisation under Article 8 of the Standardisation Regulation. As standardisation can be an essential instrument of international competitiveness, several countries are increasingly adopting integrated approaches that combine research, industrial policy and standardisation, which may facilitate a faster translation of innovation into internationally recognised standards. In this context the Commission is engaging with India under the current EU-India Trade and Technology Council to promote standards harmonisation and information sharing. International competitiveness and realising the first-mover advantages depends not only on faster standard-setting processes but also on the EU's capacity to generate the underlying measurement science and reference data and materials before its competitors. For example, China's standardisation strategy is backed by a strategic investment plan in national metrology infrastructure (5-year Metrology plan 2025-2030) as they recognise that state-of-the-art measurement capability is a precondition for influencing international technical

[441] CEN and CENELEC have implemented four main workstreams and ETSI reported to have 130 research bodies and universities as members in 2021. For further information, see Evaluation Study, p.84-85.

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standards. In the EU, these are provided, among others, by National Metrology Institutes (NMIs) and designated institutes operating within the European Association of National Metrology Institutes (EURAMET).

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ANNEX 10: DESCRIPTION OF POLICY OPTIONS

1. OPTION 1: MODERNISED ESOS' MONOPOLY

This first option **retains the core structure of the current ESS**, with ESOs remaining the only standardisation organisations entitled to receive and accept standardisation requests from the Commission. Targeted improvements are introduced to enhance responsiveness, ensure the sustainability of the ESS and foster international influence.

To address Objective 1 (improving responsiveness of the ESS), the main policy measure is to facilitate the **integration of publicly available specifications from other standardisation development organisations** (SDOs) into the ESS (*Measure 1.1*). ESOs would be incentivised or requested specifically in standardisation requests to incorporate high-quality technical standards or standardisation deliverables developed by other SDOs. ESOs are already developing this possibility under the PAS (Publicly Available Specification) process, for which they enter into structural agreements with alternative SDOs on the integration of their standards or technical specifications into their own standardisation process. This approach would enable ESOs to better leverage technical expertise where it is available and closer to the state of the art, thereby speeding up the standardisation process for critical technologies like AI, cybersecurity, or clean technologies.

An additional measure to improve responsiveness includes **the consolidation of the use of common specifications by the Commission into the Standardisation Regulation** (*Measure 1.3*). This will streamline the conditions of use and the process for the Commission to develop common specifications when ESOs fail to deliver hENs on time or meet expected quality levels. This aligns with the Omnibus IV simplification package and will further expand the use of common specifications as a fall-back option to all legislation leveraging standards to provide presumption of conformity. This measure will also clarify the interaction between common specifications and harmonised standards which ESOs have failed to deliver. It could notably allow the Commission to build on existing work conducted by the ESOs to accelerate the adoption of common specifications, while the ESOs would continue to work on delivering a harmonised standard to replace common specifications.

The option also introduces a presumption of conformity on a temporary basis for standardisation deliverables other than harmonised standards (*Measure 1.3*). This measure aims to enable faster market access for products where harmonised standards are still under development – for example, due to protracted stakeholder negotiations or technical complexities – but where essential requirements are already transcribed in a standardisation deliverable that has not yet reached the full stage of harmonised standards. In other words, this would provide a temporary presumption of conformity to a standardisation deliverable that meet essential requirements. This could, for instance, apply to the new deliverable under development by CEN and CENELEC – the European Agile Specifications (EAS) – which CEN and CENELEC consider for technical specifications reflecting a high level of consensus, but having not yet reached the maturity to be adopted as a full-fledged standard. EAS defers from a standard in two main ways: there is no public consultation before its adoption and the agreement to the deliverable can be reached at TC level after a voting procedure and does not need to reach the full consensus and approval of all Members. This instrument would also help

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harmonising conflicting national deliverables. Under this mechanism, the Commission would grant a time-limited presumption of conformity to these intermediate deliverables, with a fixed sunset clause (*e.g.* 24 months or a predefined end date), and under the condition that the standardisation process continues with the objective of transforming the intermediate deliverable into a harmonised standard.

To foster transparency and accountability with the ESS, *Measure 1.4* would improve strategic planning of standardisation, notably by improving the anticipation of standardisation needs to support upcoming policies and legislation. This would take place through a better articulation of short term and long-term standardisation needs in the Annual Union Work Programme to improve the synergies between standard developments, policy objectives and research and innovation, to improve the synchronisation of standard deliverable availability with market needs, especially in emerging sectors. The measure would also introduce Key Performance Indicators (KPIs) on the Commission's and ESOs performance to better track and report on ESOs' and Commission's performance in the standardisation process. These KPIs would for instance monitor timeliness, quality, and stakeholder participation, and would contribute to increase the accountability and transparency of the ESS. The measure would also foster regular performance monitoring, for instance through the creation of an online platform that would allow to follow the state of play of standardisation requests' execution[442]. This would allow to increase ESOs' accountability regarding their performance as well as public transparency of this performance. The introduction of a more structured institutional dialogue with ESOs (high-level structural dialogue) would also help improve transparency and accountability to the Commission and enable to identify and agree on corrective measures when deadlines are not met.

To simplify the legal process to deliver standards for Union legislation and policy purposes, another measure (*Measure 1.5*) would introduce binding deadlines at key steps in the process, especially regarding the consultation phase on draft standardisation requests, to improve the predictability of the standardisation process. It would also accelerate the decision-making process for adopting standardisation requests by **removing the requirement for comitology procedure** or at least introduce this simplification for non-essential amendments to standardisation requests, such as modifying deadlines. Furthermore, the decisions to publish references to hENs in the OJEU are currently taken by the College of Commissioners and could be delegated to responsible Director-Generals of the Commission as the publication of the references to standards is a technical assessment and does not require decisions of a political nature. To further simplify the process to deliver standards, the ESO-led digitalisation would be supported by explicitly mandating in the Regulation that requested standards be delivered in a digital format and be developed using online development tools. Last, it would introduce simplification in the formal objection mechanism to increase its legal certainty and reduce its average duration time. The simplification will introduce a collective decision mechanism on formal objections. A Member State or the European Parliament would notify the Commission and other Member States of its formal objection to a published standard, giving Member States or the Commission the opportunity to contest the relevance of the objection. In case the formal objection remains uncontested, the hENs would be automatically withdrawn. This new process

[442] A possible model for such an online platform could be the European Parliament's legislative train, which allows the public to follow the state of play of legislative initiatives.

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would bring important simplification as it would ensure that a formal objection would have an automatic formal end, thereby increasing legal certainty.

For Objective 2 (ensuring a financially viable and inclusive ESS), this option retains the current system described in the baseline **of online platforms providing read-only access to hENs on request,** in line with the Access to Documents Regulation[443]. This option also introduces **more specific and stricter requirements for NSBs to enhance civil society's participation in the European standardisation process** (*Measure 1.6)*. This measure extends the current NSBs inclusiveness best practices outlined in Article 6 of the Standardisation Regulation, which currently apply only to SMEs, to also cover civil society organisations. Based on the conclusions of the HLF report on NSBs' best practices, these include **financial incentives** (free access to draft and adopted standards, free or special rates access to standardisation activities) as well as **procedural incentives** (identification of relevant standardisation projects, possibility to participate without being a member).

This option would also introduce measures to increase **incentives to foster expert participation in standardisation** (*Measure 1.7*). The measure notably targets the **Research & Innovation community** through increased awareness efforts on standardisation in research and academic curricula, through giving pre-norms official standing, and overall foster the efforts of the Commission and ESOs to better connect research results with standards' development. This would notably include ensuring researchers have free access to the standards and draft standards relevant to their work. The awareness efforts would also be extended to experts from the industry, in particular SMEs. Last, the measure would also streamline the public financial support available for experts' participation, notably by ensuring a better articulation between the different EU programmes financing experts' participation in standardisation. The option also introduces **transparency requirements on participation** (*Measure 1.8)* in standardisation to incentivise enhanced inclusiveness in the standardisation process. ESOs would have to set up online transparency register to allow the public identification of interests represented and active in the standardisation process for hENs.

For **Objective 3 (consolidating the EU's influence in international standardisation)**, **this option introduces an EU-Member States coordination mechanism** (*Measure 1.9*) to improve sharing of information on international standardisation and foster more coherence of NSBs' and EU experts' positions in international fora. This mechanism would include regular coordination meetings chaired by the Commission to exchange on the EU perspective on key developments in ISO, IEC or ITU, while NSBs would retain the independence of their vote. The measure would include an information sharing mechanism between the Commission, ESOs and NSBs.

The option would also clarify **the possibility to restrict participation in ESOs technical committees to reliable EU/EEA actors** only in specific and targeted cases involving sensitive sovereignty or strategic areas, such as defence or critical technologies (*Measure 1.10*). Establishing a clear and legally robust definition of "European stakeholders" for participating in the standardisation process may be difficult, given the diversity of legal frameworks, corporate structures and ownership arrangements - no single criterion would necessarily ensure

[443] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31 May 2001, p 43–48.

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that entities classified as European are free from foreign influence. The measure would have to respect WTO rules that allow national preferences only under certain conditions.

The option maintains the baseline approach to international cooperation, upholding the 'international first' principle under the Vienna and Frankfurt agreements and WTO rules.

In this option, **the current governance of the ESS by the Commission would remain unchanged**.

2. OPTION 2: AN ESS CENTRED ON ESOS WITH NEW FLEXIBILITIES

This option **retains ESOs as the cornerstone of the European Standardisation System (ESS)** but departs from the baseline and Option 1 by **introducing two key innovations: alternative routes for the Commission to request standards and increased oversight of the ESS by the Commission**.

To address **Objective 1 (improving the responsiveness of the ESS)**, this option retains the integration of standards from other SDOs by the ESOs (*Measure 1.1*), **the consolidation of common specifications** in the Standardisation Regulation (*Measure 1.2*), the **temporary presumption of conformity** for standard deliverables other than harmonised standards (*Measure 1.3*), the improved **strategic planning and accountability** (*Measure 1.4*), the **simplification and digitalisation of standardisation process** (*Measure 1.5*).

However, **it introduces the possibility for the Commission to send standardisation requests to alternative SDOs other than the ESOs listed in Annex I** of the Standardisation Regulation (*Measure 2.1*). Under this option, the Commission would be empowered to address standardisation requests to other SDOs under specific conditions, such as when ESOs decline a request, fail to meet deadlines or quality expectations, or when the Commission considers that an alternative SDO would be objectively more relevant after having consulted the ESOs. This measure would thus not eliminate the ESOs' privileged position, as they would be consulted first on their ability to deliver the hEN. It would however introduce a secondary route, applying pressure on ESOs to deliver standards more efficiently by creating a competitive dynamic. To ensure sufficient quality of the provided standards and notably the inclusiveness of the process conducted by alternative SDOs, the Commission would only be authorised to rely on vetted standardisation organisations that would have to comply with criteria inspired from the current Annex II of the Standardisation Regulation that defines a quality standardisation process. Given that standards would be requested outside of the current ESS, such requests will be subject to the validation of Member States under the Comitology procedure to ensure that Member States can validate the choice of leveraging an alternative SDO. This validation by Member States is essential as the alternative SDO's development process would likely not rely on the national delegation principle and the different national interests would not be formally represented in the standardisation process managed by an alternative SDO. To ensure that all interests in the internal market are adequately reflected, the validation of the Member States through the comitology procedure is required. In addition, given that an alternative SDO might not have the same level of inclusiveness as ESOs, it will be necessary to consult the Annex III organisations before launching the comitology procedure.

This option also introduces **a Chief Standardisation Officer in the Commission, supported by an EU Experts Centre** (*Measure 2.2*). This new structure would be tasked with identifying

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and managing standardisation requests to alternative SDOs. The Experts Centre, federating public expertise on standardisation from EU institutions, agencies and Member States, would provide technical and strategic support, ensuring that requests to alternative SDOs are well-founded, aligned with EU priorities, and avoid duplication. The EU Experts Centre will also support mobilising experts in European and international standardisation and facilitate the elaboration of common specifications and the coordination of EU experts in international standardisation.

For **Objective 2 (ensuring a financially viable and inclusive ESS)**, this option introduces **free and unrestricted access to harmonised standards** (*Measure 2.3*). Access would be provided via an online portal, which could be managed either by ESOs and NSBs, as is currently the case, and / or by the Commission[444]. Unlike Option 1, which only provides restricted, read-only access upon request, this option allow unrestricted access, meaning standards could be consulted, and potentially downloaded, from the portal by any user. In practice, the measure will require setting-up a central repository, managed by the ESOs and/or by the Commission, where users can consult hENs free of charge. The measure would thus go significantly beyond the current readability platforms set up by ESOs, NSBs and the Commission, in particular as regards the conditions of access (general and non-discriminatory access, without requirements for the user to identify themselves), and the extent of access (unrestricted access would require searchable consultation features and potentially download features).

This option introduces binding requirements for NSBs to foster the participation of stakeholders (*Measure 2.4*). This would include financial incentives at national level, such as reduced fees, as well as measure to facilitate meaningful participation by SMEs and civil society representatives based on the current Article 6 of the Standardisation Regulation. The option also retains measures from Option 1 to foster expert participation in standardisation (*Measure 1.7*) and introduces transparency requirements on participation to hENs development, applying to both ESOs and alternative SDOs when relevant (*Measure 1.8*).

For **Objective 3 (consolidating the EU's influence in international standardisation)**, in addition to the improved EU coordination on positions and participation (*Measure 1.9*) and the possibility to restrict participation to standardisation to EU/EEA members (*Measure 1.10*), this option introduces a **derogation from the 'international first' principle in defined cases** (*Measure 2.5*). This would ensure the possibility to adopt hENs that reflect EU values and interests in parallel to international standards in strategic or sovereignty-sensitive areas. The measure would introduce a legal possibility to derogate from the 'international first' principle when European strategic autonomy might be limited by international standardisation activities[445]. Currently, ESOs implement the Vienna/Frankfurt Agreements without direct involvement of the Commission or EU Member States – see Annex 11. ESOs frequently offer international standards from ISO/IEC as hENs. Under the new geopolitical conditions, this might no longer be appropriate in specific cases, notably when it comes to core European

[444] Free and unrestricted access would also be granted to hENs stemming from alternative SDOs; this could be done either through the ESOs/NSBs platform or through the Commission's platform.

[445] ESOs mention that the measure can already be applied under the current Vienna and Frankfurt agreements, by specifying in the standardisation requests that hENs should be developed either at European level or with the ESOs in the lead. But this is currently not a realistic scenario, given that the ESOs do not have internal rules allowing such a scenario. Providing a legal provision in the Standardisation Regulation would oblige the ESOs to adapt their internal rules and their agreements with ISO/IEC. Targeted interviews with ESOs.

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interests, *e.g.* in dual-use goods, sensitive security issues or vital economic interests. In addition, participation of SMEs and civil society representatives may be more difficult in ISO/IEC. In such cases, the Commission would issue standardisation requests that either require the EU side to lead within the framework of the Vienna/Frankfurt Agreements or alternatively to pursue European standardisation separately from international standardisation, with a limitation of stakeholders' participation to EU-based entities as needed.

Derogations from the primacy of international standards are in principle justifiable under the WTO TBT Agreement and EU FTA. For dual-use products and technologies, an additional legal basis to introduce restrictions could be provided e. g. by the Wassenaar Arrangement[446].

3. OPTION 3: OPEN ESS MANAGED BY THE COMMISSION

This option represents a fundamental departure from the current European Standardisation System (ESS), replacing the ESO monopoly with a publicly managed system under an EU Standardisation Office. The exclusive role of ESOs (CEN, CENELEC, ETSI) in receiving standardisation requests would be removed. The system would open standardisation in support of Union legislation and policy to full competition, allowing the Commission to direct requests to any qualified SDO, while a new EU Standardisation Office for Standardisation would oversee management, coordination, and strategic alignment. Given their expertise and scope, the ESOs would still likely be addressed most standardisation requests, but the share of standards provided by alternative Standardisation Organisations could be significantly higher than in Option 2. Moreover, ESOs would no longer be consulted first on standardisation requests; the decision to which SDO to address the Standardisation Request will lie with the Commission.

To address **Objective 1 (improving the responsiveness of the ESS)**, this option retains the integration of standards from other SDOs by the ESOs (*Measure 1.1*), **the consolidation of common specifications** in the Standardisation Regulation (*Measure 1.2*), the **temporary presumption of conformity** for standard deliverables other than harmonised standards (*Measure 1.2*), the improved **strategic planning and accountability** (*Measure 1.4*), the **simplification and digitalisation of standardisation process** (*Measure 1.5*).

This option **eliminates the ESO exclusive right to receive standardisation requests entirely** by allowing the Commission to submit standardisation requests to any SDO (*Measure 3.1*). Unlike Option 2, which retains a sequential preference for ESOs, this option grants the Commission full discretion to select SDOs based solely on merit, without embedded preferences or prior obligations. Competition would be introduced through two potential approaches. The first approach involves **expanding Annex I to create a trusted list of accredited SDOs**, which would allow the Commission to choose from a pre-selected pool of SDOs meeting minimum requirements for trust, quality, and inclusiveness. The second approach adopts a **fully open competitive system**, similar to the US model[447], where the Commission could direct requests to any SDO, including industry consortia, research

[446] https://www.wassenaar.org/

[447] In the US system, any organisation (including companies, consortia, or nonprofits) can develop and publish standards, and if they meet ANSI's consensus-based criteria (e.g., openness, balance, due process), they can be adopted as national standards.

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organisations, or international bodies, without prior accreditation requirements, but with specific case by case requirements defined in the standardisation request. This model would maximise competition, forcing all SDOs – including ESOs – to compete on speed, quality, and cost to secure Commission's request.

To address Objective 2 (ensuring a financially viable and inclusive ESS), this option ensures full public access to hENs by publishing them in OJEU (Measure 3.3), replacing the current practice of only publishing a reference to them in the OJEU. This approach would remove all restrictions, making hENs available to the public in their entirety in all languages, placing hENs in the public domain. This would replace the current practice of only publishing a reference to them in the OJEU. Budgetary implications might arise where the Commission might compensate SDOs for standards' development.

To promote inclusiveness, this option **introduces mandatory participation and inclusiveness requirements for SDOs to be eligible to receive requests** (*Measure 3.4*). These requirements would include compulsory lower fees for SMEs, academia and civil society. Additional *ad hoc* requirements (*e.g.*, which specific stakeholders should be able to participate to the standardisation activities) could be inserted on a case-by-case basis in each standardisation request.

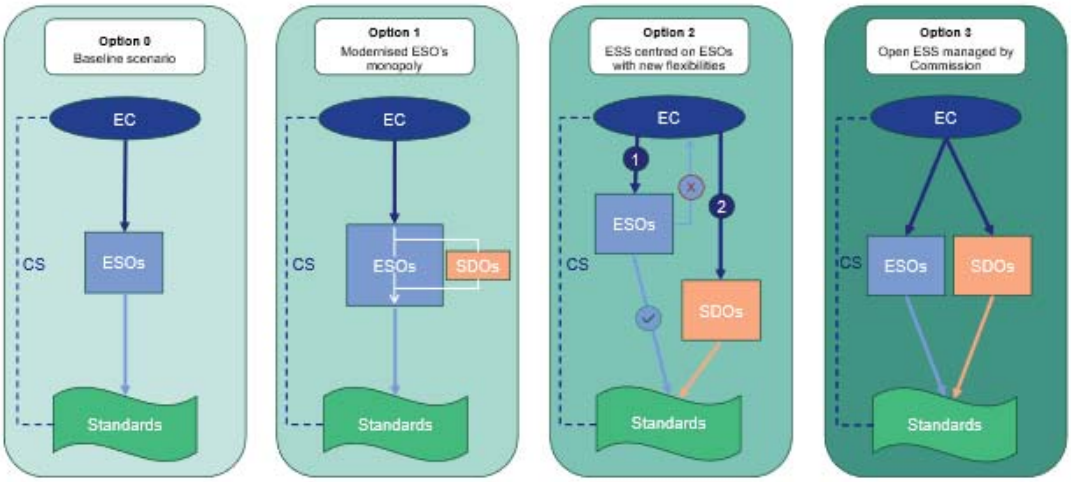
For Objective 3 (consolidating the EU's influence in international standardisation), this option retains measures introduced in Option 1 and 2 (*Measures 1.9 and 1.10*) but also provides the possibility for the **Commission to exercise full discretion on whether to align with the 'international first' principle** or prioritise EU-specific standards in strategic sectors (*Measure 3.5*). Whereas measure 2.5 maintains the central role of the ESOs and the primacy of international standards in principle, measure 3.5 would end these arrangements, *i.e.* there would no longer be a systematic preference for ESOs and ISO/IEC/ITU to elaborate technical standards; the Commission would have the choice for every standardisation request. While the majority of the requests would still likely be addressed to the ESOs, the Commission would rely on alternative SDOs for a significant number of hENs and could thus implement a more proactive and independent approach to international standardisation. Since this option introduces the possibility to choose on a case by case the SDOs requested to deliver a hEN, it would allow the EU to align standards with its priorities, values, and interests for each standardisation request, but could risk widening the gap between European and international standards.

To support the implementation of all measures, this option establishes an **EU Standardisation Office** (*Measure 3.2*). The Office would identify the most appropriate SDO for each standardisation request to improve responsiveness (Objective 1), oversee potential compensation for standards development or acquisition to ensure access and inclusiveness (Objective 2), and identify EU priorities, monitor international standardisation work, and coordinate EU positions in global fora to strengthen global influence (Objective 3). The office would regroup all Commission resources actively engaged in implementing the Standardisation Regulation, introducing a centralised governance model replacing the current governance**,** where each service is responsible for the implementation of standardisation requests in its field of activities.

Figure 10.1 summarises the different paths for requesting hENs under each policy option.

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Figure 10.1: Paths for requesting harmonised under each policy option



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ANNEX 11: SYSTEMIC DIFFERENCES BETWEEN EUROPEAN STANDARDISATION AND OTHER COUNTRIES

The European Standardisation System (ESS) is worldwide unique, due to

a) its intricate links with European legislation through the New and Global Approach, the New Legislative Framework (NLF) and EU free trade agreements (FTA),
b) its integration with international standardisation,
c) its design as a public-private partnership – a compromise between direct governmental control and a private-sector-driven bottom-up approach.

1. LINKS WITH EUROPEAN LEGISLATION

European standards have been a key tool to eliminate non-tariff barriers among EU Member States. Under the traditional 'Old Approach' detailed mandatory specifications were imposed by EU legislation, often after lengthy negotiations with EU Member States. From 1985, the 'New Approach' restricted the content of mandatory legislation to 'essential requirements' leaving technical details to European harmonised standards. As the New Approach turned out to be very successful, it spread into many areas of standardisation through the 'Global Approach' and finally the 'New Legislative Framework' (NLF) from 2008. Together with the NLF, the EU now has a comprehensive package of regulation, from standardisation to conformity assessment, accreditation and market surveillance, including the control of products from outside the Union.

The EU has been promoting this system in international fora such as the World Trade Organization (WTO) and through free trade agreements (FTA) with third countries. EU FTAs stipulate in particular the primacy of international standards to avoid technical barriers to trade, in accordance with the WTO TBT Agreement. Although exceptions are possible under certain conditions, WTO rules in principle bind its members and are subject to WTO dispute resolution mechanisms. Besides, FTA provisions are part of international law and therefore binding for the contracting parties, becoming part of their domestic legal order.

2. INTEGRATION WITH INTERNATIONAL STANDARDISATION

For the purposes of technical standardisation, the Standardisation Regulation recognises ISO, IEC and ITU as international standardisation bodies. ISO and IEC are private-sector organisations that gather the national standardisation bodies from most countries in the world. National standardisation bodies of EU Member States are all members of ISO and IEC, while the Commission has liaison status only in certain technical committees. ISO/IEC and CEN/CENELEC are closely cooperating on the definition and the improvement of their standardisation processes; they are notably implementing joint tools to foster online standards development to speed up standardisation and facilitate access.

CEN and CENELEC have cooperation agreements with ISO and IEC respectively that organise the articulation between the European and the international systems – the Vienna and Frankfurt Agreements. While each agreement has its own specificities, they both aim at ensuring the primacy of international standards and avoiding duplicative or competing standards development leading to conflicting standards at European and international levels. In practice, these agreements ensure that European and international standardisation organisations agree

which new standardisation projects are undertaken jointly and who is going to take the lead – generally the international level. Resulting standards are then voted on and adopted in parallel, with some adaptations if needed. Once international standards have been adopted as European standards, the national standardisation bodies of CEN-CENELEC have to transpose them into national standards and withdraw any conflicting standard. The Vienna and Frankfurt agreements thus operationalise the 'international first' principle, whereby i) the opportunity to conduct standardisation activities in a specific field should be first investigated at international level and ii) European standards should in principle not compete with international standards, unless under special circumstances.

As a consequence, more than one third of CEN's portfolio (European standards and European standardisation deliverables) is identical to, or based on, ISO standards while this proportion reaches 81 % for CENELEC standards in relation to IEC standards[448]. Moreover, the alignment also concerns the standards supporting Union legislation and policy by the Commission: 28 % of deliverables requested to CEN by the Commission are identical to, or based on, ISO standards and 65 % of deliverables requested to CENELEC are identical to, or based on, IEC standards.

The case of ETSI is different, since it allows direct membership of companies and stakeholders, with over 900 members from more than 60 countries. ETSI too is highly involved in international standardisation, but with a different model of engaging in partnership agreements with international, regional and national organisations to jointly deliver standards with international reach. ETSI is both a European Standardisation Organisation and a globally recognised Standards Development Organisation (SDO) - it aims at developing standards that are both European and international. It has no Frankfurt or Vienna-type agreements with international standardisation bodies and no special status at ITU, as ITU is a specialised UN agency for ICT and telecommunication technologies, having countries as principal members. ETSI is however actively engaging in international standardisation through cooperation agreements. It has developed over the years a partnership portfolio to establish consistency between ETSI standards and its partners, to avoid duplication of efforts, increase convergence of technologies and foster the outreach of ETSI standards. ETSI is for instance a founding partner of global partnerships such as 3GPP and oneM2M.

3. PUBLIC-PRIVATE PARTNERSHIP VS. DIFFERENT GOVERNANCE MODELS

Over the course of several years the **ESS** has developed together with EU efforts to create and deepen the internal market. It is based on a public-private partnership between government entities, European and national standardisation bodies, companies and other relevant stakeholders – a complex system with many checks and balances to ensure legitimate public and private interests. Although technical standards have never been neutral or purely technical matters, they rarely appeared on the political agenda in the past, neither in Europe nor elsewhere. Standards have now become part of industrial policy, the weaponisation of economic ties and broader security issues. National governments pay more attention to standardisation and try to use it for their purposes.

[448] CEN CENELEC in figures - Quarterly, 2026 Q1

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China has particularly high ambitions in standardisation, as well as the ability to closely align political will with significant national resources and implementation on the ground. Under the old Communist system, Chinese standards were mandatory and directly written by sectorial ministries. After successive reforms, China now has both mandatory and voluntary national standards, in addition to local/regional and industry standards as well as company and association standards; none of them are mandatory, unless they get officially endorsed as such by the Standardization Administration of China (SAC), a government body. Each type of standards has its own standardisers who do not necessarily coordinate or cooperate, leading to many competing and overlapping domestic standards. The relatively new association standards were created to allow for bottom-up, industry-driven standardisation like in the US. In practice, nothing happens without government oversight, and the system remains state-driven, rather unwieldy and opaque. Despite these domestic issues, SAC has pursued an active policy to increase the participation of Chinese experts in international standardisation organisations, such as the ITU, ISO, IEC or 3GPP - with some success. Chinese standardisers often get subsidies if they manage to export Chinese content to the international level, which explains part of the quantitative increase of China's role in international standardisation. In parallel, China also tries to impose its standards in bilateral relations with other countries, through mutual recognition or the Belt & Road Initiative. Chinese standardisers benefit from political support and extensive, well-resourced domestic training programmes. Standards are a priority in China, also as a tool to boost quality and technological advances.

Systematic industrial standardisation in **Japan** began in 1921, when a study committee established 520 "Japanese standards" and then 931 "Tentative Japanese standards" primarily for military-use commodities. After WW2, standardisation played a significant role in improving the quality and competitiveness of Japanese products, as part of Japan's industrial policy that accompanied the rise of its industry. Today, Japan's national standardisation body is the Japan Industrial Standards Committee (JISC), under the jurisdiction of the Ministry of Economy, Trade and Industry (METI). JISC has been an active member of both ISO and IEC, representing Japan in these organisations. There are some 11 000 voluntary Japan Industrial Standards (JIS) administered by JISC/METI and made available by the Japan Standards Association (JSA).

The **United States** appears to be shifting towards a more government-driven style on standardisation, away from its traditional bottom-up, market-driven approach - the 2025 National Security Strategy is a case in point.[449] The American National Standards Institute (ANSI) was first established as the American Engineering Standards Committee in 1918, but never had the power to coordinate the many different American standards developers; it does however represent the US at ISO and IEC. US standardisation is private-sector-led, where multiple stakeholders try to achieve a voluntary consensus, based on general principles. US standards are not binding, unless made obligatory by specific legislation. Industry consortia play an important role in international ICT standardisation. Despite this private-sector-led approach, the US federal government is an important user of specifications and standards, with more than 44 000 distinct statutes, technical regulations or purchasing specifications. The National Institute for Standards and Technology (NIST – a government agency) also develops standards, such as the Federal Information Processing Standards (FIPS), and engages with

[449] National Security Strategy of the United States of America, November 2025, The White House / Washington.

international counterparts. Adding the more than 50 000 standards estimated to come from the private sector, the total inventory approaches 100 000 standards, produced and maintained by hundreds of standards organisations in the US[450].

The following table 11.1 highlights key differences between standardisation systems in the EU, China, Japan and the US[451].

Table 11.1: Comparison between the EU, Chinese, Japanese and United States' approach to standardisation for public policy purposes

	European Union	**United States**	**China**	**Japan**
Standard-setting system	The Commission can mandate the development of harmonised European standards to designated European standardisation organisations to support EU laws/legislation. The standards are hence developed based on a standardisation request based on the needs of the Commission. This process is organised by Regulation (EU) 1025/2012. EU legislators can also	No government-mandated standards. Decentralised system with approximately 300 Standards Development Organisations (SDOs). Standards can compete and can conflict. Standards-development is fully left 'to the market'. The legislator decides which standards are referenced (and made mandatory) in U.S. legislation.	Standards can be government-developed and private. ▪ Government-developed standards: SAC (Standards Administration of China) develops national standards (compulsory and voluntary), promulgated in the name of the State Council. In addition, voluntary local standards can be formulated by provincial or municipal governments and must be filed with the SAC and relevant State Council departments.	No government-mandated standards. The national standardisation body JISC (Japanese Industrial Standards Committee) is part of Japanese government/METI (Ministry for Economy, Trade and Industry) but works independently, in accordance with the WTO TBT Annex III criteria. It develops national standards, not necessarily at the request of the Japanese government but based on stakeholder requests.

[450] Overview of the U.S. Standardization System
[451] Evaluation of the Standardisation Regulation, Annex X.

	European Union	United States	China	Japan
	directly reference standards (not only European ones) in secondary legislation (this process is not regulated by Regulation (EU) No 1025/2012).		▪ Private standards: this includes association/ group standards (adopted by academies, associations, chambers of commerce, and federations) and enterprise standards (functional or performance indicators of products or services). Group standards do not require government approval, but their formulation is subject to the regulation, guidance, and supervision of the SAC and relevant State Council departments.	In a Japanese law from 2018, any Japanese standards organisation can ask JISC to be accredited to prepare national JIS standards.
Main actors	European standardisation organisations CEN, CENELEC and ETSI; national standardisation bodies. Industry-driven consortia also exist, but are not defined in	Hundreds of stakeholder driven standards-development organisations. The American National Standards Institution (ANSI) is an umbrella	Government-developed standards: Standardisation Administration of the People's Republic of China (SAC): unified management, supervision and overall coordination of	JISC (Japanese Industrial Standards Committee).

	European Union	United States	China	Japan
	the EU Standardisation Regulation and only play a role in the Regulation in the context of ICT specifications.	organisation (does not draft standards, but issues American national standards and accredits U.S. standardisation organisations as responding to the WTO TBT Annex III criteria).	standardisation work in China. State Council Departments Ministries and other bodies such as Ministry of Industry and Information Technology (MIIT), Ministry of Environment, Ministry of Transport, responsible for drafting standards, soliciting public opinions and formulation of standards. Provincial/municipal governments Private standards: associations, industry, individual companies.	
International representation	ISO/IEC: CEN is an observer in ISO. CENELEC is an observer in IEC. There is an enshrined cooperation between both organisations. The members of CEN and CENELEC (national standardisation bodies) are also members of	ISO/IEC: ANSI represents the U.S. by coordinating the U.S. national delegation formed by sector experts. ITU: Different government departments.	ISO/IEC: SAC represents China. SAC is responsible for organising the activities of the Chinese National Committee for ISO and IEC. SAC approves and organises the implementation of international cooperation and the exchange of projects on standardisation.	JISC represents Japan in ISO/IEC. Japan has a similar attitude to the European one regarding international standards, and also a similar degree of implementation of international standards as national ones.

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	European Union	United States	China	Japan
	ISO and IEC, respectively. ITU: national governments, the European Union is observer.		ITU: Ministry of Industry and Information Technology (MIIT) represents China.	

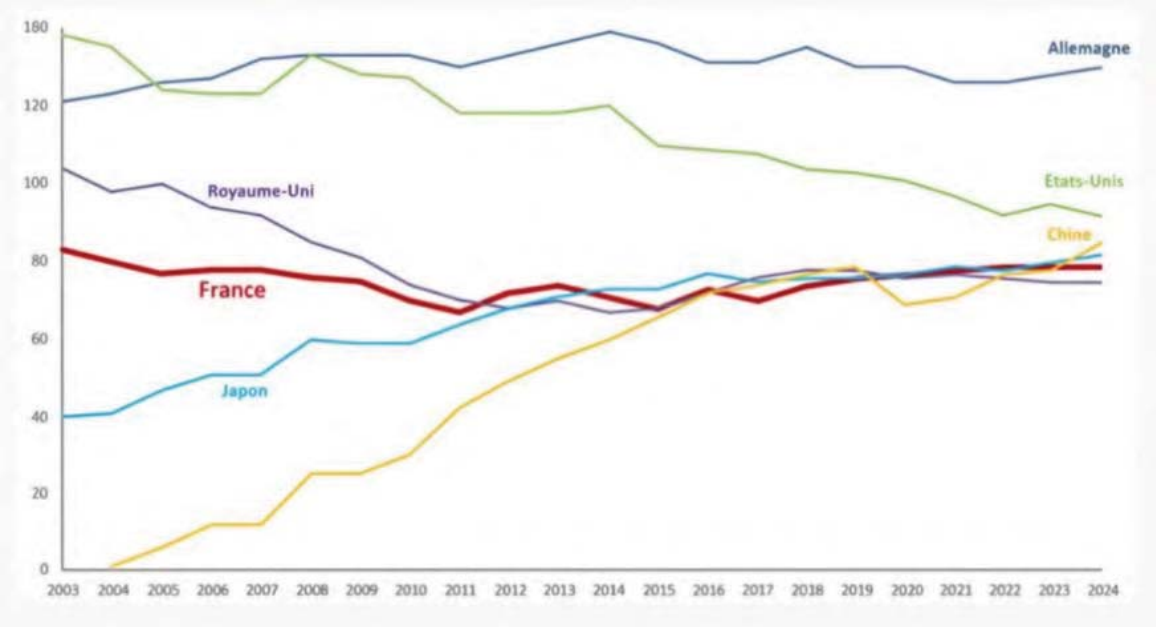
In this new global environment, Europe's hybrid model, combining EU guidance with a bottom-up process that involves companies and stakeholders, has both strengths and weaknesses. The subject attracted new interest from academics and think tanks[452]. The EU model now has to compete directly with powerful, coordinated efforts by other global actors, including large multinational ICT companies that try to impose their own standards.

So far, the NSBs of EU Member States maintain an active role in international standardisation, highlighted by Figure 11.1. However, China is catching up fast and Japan (JISC) has also increased the number of its secretariats in ISO technical committees over the years.

Figure 11.1: Evolution of number of active technical committee secretariats at ISO (2003-2024 / national NSBs)[453]

[452] For example: Raising the standard: How to unlock the geopolitical potential of Europe's internal market - Clingendael Report, October 2025: Raising the standard: How to unlock the geopolitical potential of Europe's internal market | Clingendael; Technological evolution, looming geopolitics. Embarking on 6G standards definition - The Swedish Institute for International Affairs, 2025: ui-brief-no.-6-2025---6g-standards.pdf; The geopolitics of technology standards: historical context for US, EU and Chinese approaches - International Affairs, Volume 100, Issue 4, July 2024: geopolitics of technology standards: historical context for US, EU and Chinese approaches | International Affairs | Oxford Academic

[453] AFNOR, Diplomatie des normes la France à la croisée des chemins, 2025



The influence of the EU is however less strong in new strategic technologies, as illustrated by table 11.2.

Table 11.2: Leadership in key ISO Technical Committees[454]

Technical Committee	Title	Published standards	Standards under development	Secretariat/NSB
ISO/IEC JTC 1	Information technology	3 680	570	US
IEC/ISO JTC 3	Quantum technologies	1	1	UK
ISO/TC 20	Aircraft and space vehicles	692	107	US
ISO/TC 197	Hydrogen technologies	26	23	Canada
ISO/TC 204	Intelligent transport systems	369	72	US
ISO/TC 229	Nanotechnologies	117	35	UK
ISO/TC 276	Biotechnology	48	45	Germany
ISO/TC 298	Rare earth	15	7	China
ISO/TC 299	Robotics	33	24	Sweden
ISO/TC 301	Energy management and energy savings	22	3	US
ISO/TC 333	Lithium	1	17	China

[454] https://www.iso.org/technical-committees.html

ANNEX 12: CURRENT COMMISSION GOVERNANCE TO MANAGE THE ESS

1. RESOURCES TO MANAGE THE ESS IN THE COMMISSION

The Commission's standardisation activities are managed by 16.5 FTEs within DG GROW's dedicated Standards Policy Unit, which is responsible for overseeing and managing the implementation of the Standardisation Regulation and more generally the ESS framework. Additionally, around 60 staff members from various Commission services, representing 30 FTEs[455], including the European Innovation Council as well as the European Innovation and SMEs Executive Agency (EISMEA), are involved in developing standardisation requests on a yearly basis, monitoring the technical work of ESOs to deliver on these standardisation requests and assessing the offered standards against the essential requirements set out in the standardisation requests. They also monitor and participate in European and international standardisation work of relevant SDOs, fora and consortia on topics related to EU policies. In addition, the Commission provides technical and scientific expertise to the standardisation work of ESOs, ISOs and SDOs through the participation of 35 to 80 staff members from the Joint Research Centre (JRC), who support the development of standards in their areas of scientific expertise.

The ESS is supported by the Single Market Programme (SMP) with an average annual budget for standardisation activities of EUR 24 million. EUR 6 million are allocated to the three ESOs through operating and action grants to finance the functioning of the ESS and investments for its improvements, notably digitalisation. EUR 5.4 million are directed toward Annex III organisations (SBS, ANEC, ECOS, and ETUC) to promote inclusiveness for small and medium-sized enterprises, consumers, and civil society in the European standardisation process. EUR 3 million support the Commission's internal operations, including the maintenance of IT systems and the outsourcing of assessment tasks to HAS Consultants. The remaining EUR 9.6 million are dedicated to action grants for specific standardisation priorities. While these grants are addressed to the ESOs, they ultimately benefit industry experts involved in the development of standards by covering the costs of their participation. This budget is expected to remain stable in the ongoing discussions of the Multiannual Financial Framework (MFF).

European standardisation is also supported through other EU financing programmes that aim at fostering experts' participation in technical work, notably Horizon Europe and the Digital Europe Programme. The budget for ongoing projects related to topics such as ICT,

[455] Most Commission services use the ESS to support their legislation and policy. The most active users are DG CLIMA, DG CNECT, DG DEFIS, DG ENER, DG ENV, DG GROW, DG JUST, DG MOVE, DG SANTE and DG TAXUD. Resource involvement from these services may vary significantly from one year to the next, depending on their standardisation needs. The Excellence Hub on Standardisation that connects Commission officials involved in standardisation mobilises 60 persons on average (out of a total of over 300 colleagues registered), which is a good indicator of the actual number of staff engaged in standardisation activities at any point in time. The actual contribution of each person involved is estimated at 50 % as this significantly vary from one service to the next.

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cybersecurity, AI and blockchain in standardisation is EUR 23.5 million[456] while future projects foreseen under Horizon Europe and the Digital Europe Programme add up to over EUR 19.5 million[457].

2. THE HIGH-LEVEL FORUM ON EUROPEAN STANDARDISATION

The High-Level Forum on European Standardisation (HLF or the Forum) was established in January 2023 as a key initiative under the EU Standardisation Strategy, with the primary aim of providing **high-level advice and support to the European Commission on standardisation policy**. Its mission focuses on enhancing the European standardisation system to support a green, digital, and resilient internal market.

The Forum's mandate has been prolonged for 3 additional years until the end of 2028.

2.1. Functioning of the Forum

The HLF currently has 56 members: the 27 Member States and Norway, the 3 European Standardisation Organisations, the 4 Annex III organisations (SBS, ANEC, ECOS and ETUC) as well as industrial associations of 17 sectors. It includes 1 university, 1 research association and 2 SME associations.

To support its technical work, the HLF can also rely on ad-hoc external experts, upon agreement of its members. National Standardisation Bodies can also participate in the discussions upon invitation.

The Forum is organised in 3 different layers:

- the **main group,** where members are represented at senior level (CEO , Minister, State secretary), chaired by one of the Commission Executive Vice-Presidents . It generally meets once per year.

- the **sherpa group:** the main group is supported by a **group of sherpas** who conduct the technical work. Members can be represented by up to 3 Sherpas, one for each sector of expertise (green, digital and resilience). The sherpa group is chaired by the Director of GROW H and convenes 3-4 time per year to prepare proposals to the main group for final endorsement.

- **thematic groups** (**workstreams**), selected according to topic relevance: workstreams regroup voluntary members (at least six), are led by one or two members and supported by the relevant Commission services. During the first mandate of the HLF, 16 workstreams and one thematic analysis have been carried out.

The final **deliverables** (recommendations, reports) of the Forum are generally prepared within the thematic groups and then **endorsed by the Forum** through a two-step validation process,

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[456] *E.g.* INSTAR EUR 1.5 million, StandICT.eu 2026 and 2029 EUR 4.5 million and EUR 6 million respectively, SeeBlocks EUR 1 million and ADRA-e EUR 4 million.
[457] *E.g.* SNS ICE EUR 3 million, standards for Quantum Technologies EUR 1 million, standardisation for the EuroQCI EUR 3 million and Future StandICT.eu EUR 7 million.

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first at sherpa group level and then formally by the main group. The Forum can also adopt horizontal recommendations prepared directly at sherpa level. Deliverables are publicly available[458].

2.2. Key achievements of the Forum

Over its initial three-year term, the Forum has played a crucial role in aligning standardisation priorities with EU policies and legislation, fostering dialogue among diverse stakeholders. **It filled a gap by coordinating the very diverse stakeholders active in standardisation** and was instrumental in the implementation of the 2022 Standardisation Strategy. It contributed to build the current consensus that **EU standardisation policy should also be considered as a tool for industrial policy**, and not merely as a technical topic.

Improved strategic coordination is particularly important and needed in international standardisation where EU Member States and NSBs actively participate whereas the Commission does not enjoy membership rights in key organisations (see Annex 11). Furthermore, a 'Team Europe' spirit tends to increase the involvement and commitment of European experts, particularly if it produces concrete results. For example, the EU and Member States successfully supported the creation of a Joint Technical Committee at ISO/IEC on the Digital Product Passport, a key EU project. Besides, substantive recommendations for increased inclusion of civil society and SMEs in standardisation at international level were made by the relevant HLF thematic group. The HLF will thus continue its work in these important areas.

Its multi-stakeholder approach was recognised as a model for inclusive consultation and timely consensus building; **national mirror fora** were established according to its model by some Member States.

The HLF also produced concrete deliverables that are considered as reference documents by stakeholders.

- **On cross-cutting standardisation topics**: the HLF adopted recommendations on increasing funding for standardisation activities at international level, on improving the inclusiveness of the standardisation process at national and international level, as well as on improving education and skills for standardisation. The latter recommendation included a voluntary pledge by members to invest more in education and skills and the introduction of a Pan-European Certificate of Knowledge in Standardisation. The Forum also contributed to the better planning of the European standardisation activities by advising on future standardisation needs in the framework of the Annual Union Work Programme for European Standardisation (AUWP).

- **On sectoral standardisation priorities**: the HLF adopted recommendations on Quantum, Green Electricity systems, Smart and sustainable cities, Critical raw materials, Clean Hydrogen and Wind Power. It also adopted recommendations on Data interoperability and Low Carbon Cement that provided direct contributions to two standardisation requests. The workstream on the Digital Product Passport (DPP)

[458] On the Commission website: https://single-market-economy.ec.europa.eu/single-market/goods/european-standards/standardisation-policy/high-level-forum-european-standardisation_en.

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contributed to consensus building to amend the respective standardisation request. The workstream on Artificial intelligence delivered around 65 AI standards awareness-raising activities during 2024/2025.

2.3. Priorities and proposed workplan for the new mandate

The Forum decided to engage in the following tasks and activities for the second mandate:

(1) Support the Commission in the revision of the Standardisation Regulation. The Forum could in particular serve as a ‘sounding board’ to test the relevance and acceptability of proposed policy orientations.

(2) Issue technical and policy recommendations on priority standardisation topics, prepared in dedicated thematic workstreams.

(3) Monitor the implementation of the recommendations endorsed during the first mandate.

(4) Contribute to the identification and dissemination of best practices in standardisation across Member States and sectors.

The Forum contributes to the yearly strategic planning and AUWP on standardisation. Based on the EU policy objectives and feedback from the members, the following priorities areas have been identified and planned. For 2026, Education & Skills on standardisation, Global standard setting and the EU position, Digital Product Passport, Quantum, Electricity System for Energy Transition, Standardisation for dual-use technologies. For 2027, Funding and investment in standardisation, Synergies with Research & Innovation policy, EU Digital Transformation of Quality Infrastructure, Innovative Ports & Terminals, Bio-Economy. For 2028, topics will be selected according to future needs.

ANNEX 13: ALTERNATIVE STANDARDS DEVELOPING ORGANISATIONS (SDOS)

1. INTERNATIONAL STANDARDISATION BODIES

Art. 2(9) of Regulation (EU) No 1025/2012 (the Standardisation Regulation) specifically states that the definition of 'international standardisation body' means the International Organisation for Standardisation (**ISO**), the International Electrotechnical Commission (**IEC**) and the International Telecommunication Union (**ITU**). There is a consensus in all jurisdictions that these bodies are leading international standardisation organisations which fulfil all core principles for the development of international standards established by the WTO/TBT Committee in its "Decision on Principles for the Development of International Standards"[459] (originally adopted in 2000). This Decision provides six core principles - transparency; openness; impartiality and consensus; effectiveness and relevance; coherence; development dimension - to ensure international standards facilitate global trade rather than create technical barriers. These principles guide whether standards are considered "relevant" under the TBT Agreement.

In line with the above, policy makers around the world have confidence that by using IEC, ISO or ITU International Standards for regulatory purposes they comply with their WTO obligations under the Technical Barriers to Trade Agreement and are thus not creating any unnecessary obstacles to international trade. Hence, also the EU has facilitated the legislative use of such standards, either by allowing their incorporation into European harmonised standards or by directly referencing to such standards in EU law. Additionally, references to ISO, IEC or ITU standards done within European harmonised standards (so-called 'normative references') are accepted in principle.

2. OTHER RELEVANT INTERNATIONAL SDOS

While there is thus consensus over the three-above mentioned organisations as recognised international SDOs, the global standardisation landscape encompasses a myriad of additional bodies, acting at either sectoral, national, regional or global level. Certain of these SDOs have been implicitly recognised by the EU as international SDOs via their inclusion in some of the FTAs signed with third countries. These entities are:

- **Codex Alimentarius** Commission;
- International Civil Aviation Organisation ("**ICAO**");
- World Forum for Harmonisation of Vehicle Regulations (WP.29) within the framework of the United Nations Economic Commission for Europe ("**UNECE**");
- United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals ("**UN/SCEGHS**");
- International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**");
- International Maritime Organisation ("**IMO**");
- International Organisation of Legal Metrology ("**OIML**");
- International Olive Council ("**IOC**");
- Universal Postal Union ("**UPU**");

[459] WTO | Principles for the Development of International Standards, Guides and Recommendations

- Bureau International des Poids et Mesures ("**BIPM**").

3. US SDOS FOR WHICH THERE IS NO CONSENSUS ON THEIR INTERNATIONAL STATUS

However, there are several other SDOs for which there is no consensus on their status s international standardisation bodies, with different views e.g. between the EU and the USA. For the EU, EFTA, EU Member States, European and national standardisation bodies of the EU/EEA and many European stakeholders, an international standard is a standard drafted complying with the WTO/TBT Committee's Decision on Principles for the Development of International Standards, Guides and Recommendation (first criterion), but by a recognised international standard body (i.e., ISO-IEC-ITU) or by an international treaty organisation such as Codex Alimentarius, UNECE etc (second criterion).

To the contrary, for the USA the application of the WTO TBT Committee Decision is a necessary and sufficient condition to qualify an SDO as an international standardisation body, while for the EU it is a necessary condition but not sufficient.

The WTO/TBT Committee Decision on the Principles for the Development of International Standards does not represent a legally binding definition for the term of "international standard". Therefore, the EU view is that neither properly developed European standards from CEN/CENELEC/ETSI (ESOs), nor those from US-based standardisation organisations (e.g., ASTM, ASME, IEEE, SAE…) can be considered as "international standards", although they may have been developed in accordance with the WTO/TBT principles.

This difference of interpretation concerns many leading SDOs based in the USA, like e.g. the American Society for Testing and Materials (**ASTM International**), the Institute of Electrical and Electronics Engineers (**IEEE**), the Society of Automotive Engineers (**SAE International**) or the American National Standards Institute (**ANSI**). The fact that the EU does not recognise these entities as international SDOs means that their standards are not accepted as normative references in European harmonised standards. Nevertheless, from a technical point of view the standards developed by these entities might be the most used globally in certain sectors and for certain products.

4. OTHER SDOS ACTIVE IN FIELDS REGULATED BY EU LAW

Independently from the discussion on the status of international SDO or not, many SDOs develop standards and/or technical specifications, particularly in the digital sector, which are of global relevance and are broadly accepted and used by the market. Some are entities which comply with the WTO/TBT principles; some others are purely private consortia with no such claim. But the fact that in some cases there is no way around the standards/specifications developed by these other SDOs is at the basis of Art. 13 of the Standardisation Regulation, which provides for a process to give legal value to ICT technical specifications for the purpose of public procurement, in specific circumstances and under a set of criteria defined in Annex 2 of the regulation.

Some of the most relevant SDOs active in digital standardisation are:

- W3C - World Wide Web Consortium (**W3C**), which develops standards and guidelines to facilitate a web based on the principles of accessibility, internationalisation, privacy

and security. Their guidelines are the basis and incorporated into the harmonised standard to support eAccessibility and the Web Accessibility Directive. And many W3C standards are being considered in the context of the EIDAS Regulation and EU Digital Identity Wallet, on web authentication, verifiable credentials.

- **OASIS Open**: The Organization for the Advancement of Structured Information Standards, also known as OASIS Open, is an industry consortium that develops technical standards for information technology.

- The already mentioned Institute of Electrical and Electronics Engineers (**IEEE**), which develops global standards in a broad range of industries, including: power and energy, artificial intelligence systems, internet of things, consumer technology and consumer electronics, biomedical and health care, learning technology, information technology and robotics, telecommunication, automotive, transportation, home automation, nanotechnology, information assurance, emerging technologies, and many more.

- **Ecma International**: is a non-profit organization that develops standards for information and communication technologies. It covers topics such as natural language interaction, information storage, programming languages or software and system transparency, amongst others.

- **GS1**: their standards enable organisations to identify, capture and share information smoothly, creating a common language that underpins systems and processes all over the world. GS1 standards could be relevant in the context of product information and e-commerce, such as barcodes, QR code or RFID.

- **3GPP**, which produces Technical Specifications in the domain of mobile communications (3G, 4G, 5G, 6G), to be transposed by seven Standardisation Bodies from EU, US, China, India, Japan and Republic of Korea (Organisational Partners) into their appropriate deliverables (e.g., standards). This is done by ETSI for the EU.

- **oneM2M** sets standards for the Internet of Things, by creating the global technical standard for interoperability concerning the architecture, API specifications, security and enrolment solutions for Machine-to-Machine and IoT technologies based on requirements contributed by its members. Their standards are also often transposed in the EU via ETSI standards.

- **Linux Foundation** Europe: some Linux Foundation hosted projects have been initiators of international standards, brought to ISO/IEC through the PAS process, e.g. for interoperable and secure EV charging.

- **Eclipse Foundation** (strictly speaking not an SDO, but an Open-Source organisation): their specifications drive open-source collaboration and innovation Eclipse Foundation actively contributes to the standardisation work related to the Cyber Resilience Act.

- OpenID Foundation (**OIDF**) is a non-profit organisation established in 2007 that develops and promotes open standards for digital identity and authentication, facilitating secure online interactions across various platforms. OpenID standards are being

considered in the context of the EIDAS Regulation and EU Digital Identity Wallet, on issuance of verifiable credentials or identity assurance.

The above is a representative, but by far non-exhaustive list of SDOs which contribute significantly to shape the technical state-of-the-art for important market sectors. But there are many more, in all types of sectors and technologies, that are or would be potentially very useful for legislative purposes. For instance, the European Health Data Space will necessarily have to be supported for its implementation by technical specifications developed by SDOs like Health Level Seven International (**HL7**)[460], **SNOMED**[461], Integrating Healthcare Enterprise (**IHE**), and others.

Other examples of SDOs which produce standards that are relevant for EU legislation and policies are the European Organisation for Civil Aviation Equipment (**EUROCAE**) which deals exclusively with aviation standardisation, for both airborne and ground systems and equipment; or **ASD-STAN**, an association which establishes, develops and maintains standards on behalf of the European aerospace industry. Over the years, ASD-STAN has established a standardisation process for European aerospace standards in agreement with the European Committee for Standardisation (CEN), but there have been some problems in the mutual collaboration, e.g. from the angle of inclusiveness of the ASD-STAN system as per relevant provisions in the Standardisation Regulation. For financial reporting standards, an important entity is the European Financial Reporting Advisory Group (EFRAG), established in 2001 with the encouragement of the European Commission to serve the public interest. In 2022, the group extended its mission to providing technical advice to the European Commission in the form of fully prepared drafts of EU Sustainability Reporting Standards (CSRD).

In the field of railway transport, the standards developed by the International Union of Railways (French: *Union internationale des chemins de fer*, **UIC**), an international rail transport industry body founded in 1922 and based in Paris, play an essential role in the sector. It has a structural collaboration with the European Union Agency for Railways (ERA), and the standards and technical specifications developed by UIC are at the basis of railways interoperability and railway communications technology, like e.g. the next-generation Future Railway Mobile Communication System (FRMCS) programme, currently under development, which plays a very important role in EU transport policy.

In the USA alone, where the standardisation system is not as regulated as in the EU, the federal administration, the state-level administrations and the public agencies rely on standards and technical specifications developed by hundreds of different SDOs, consortia and industry associations. Most of these entities do however not comply with the WTO/TBT principles, and their standards/specifications do not have in most cases global technical relevance. Also, not all of these entities do for instance offer licensing based on fair, reasonable and non-

[460] HL7 is a non-profit, ANSI-accredited organisation providing international standards for the exchange, integration, sharing, and retrieval of electronic health information. HL7 standards enable different healthcare systems to securely communicate patient data, such as lab results and administrative records.
[461] SNOMED International is an international non-profit standards development organisation, located in London, UK. SNOMED International is the trading name of the International Health Terminology Standards Development Organisation (IHTSDO), established in 2007.

discriminatory (FRAND) conditions for IPRs essential to the implementation of their standards/specifications.

ANNEX 14: RELEVANT JURISPRUDENCE ADDRESSING PROVISIONS OF THE STANDARDISATION REGULATION

1. CASE C-613/14 JAMES ELLIOTT CONSTRUCTION LTD V IRISH ASPHALT LTD

The first ruling of the Court of Justice of the European Union (CJEU) concerning harmonised standards was delivered in case C-613/14 James Elliott Construction Ltd v Irish Asphalt Ltd on 27 October 2016. The case was referred to the CJEU by the Irish Supreme court for a preliminary ruling, requiring the CJEU to provide guidance on the relevant EU law, under Article 267 TFEU. At national level, the construction company James Elliott Construction Ltd sought compensation from the cement aggregate supplier Irish Asphalt Ltd before the Irish Supreme Court, as their cement caused damage to a construction […]. The plaintiff alleged that the supplied products did not comply with the Irish transposition of standard EN 13242:2002, harmonised with the Construction Products Directive 89/106/EEC, and published in the Official Journal of the European Union (OJEU). The Irish Supreme Court referred specific questions to the CJEU concerning the legal nature of European harmonised standards and the status of national standards adopted pursuant to a harmonised standard, the scope of jurisdiction of the CJEU, the interpretation of the scope and content of European standards, in particular as regards presumption of conformity, and rules for its rebuttal.

These questions were crucial in determining whether the product of Irish Asphalt, which complied with the harmonised standard, the reference to which was published in the OJEU, met the necessary requirements under EU law.

The key findings of the Court to note are:

1. Harmonised standards are part of EU law

Harmonised standards, developed by European standardisation organisations under a mandate from the European Commission, form part of EU law. While these standards are voluntary, compliance with them confers on them a presumption of conformity with the essential requirements set out in EU secondary legislation, thereby allowing products to be placed on the market. Therefore, harmonised standards form part of EU law.

2. Jurisdiction of the Court of Justice

The CJEU has jurisdiction over the interpretation of harmonised standards when they are linked to EU secondary legislation. This ensures uniform application of these standards across the EU and reinforces the role of the CJEU in resolving disputes involving harmonised standards.

3. Presumption of conformity

Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with EU secondary legislation.

4. Voluntary Nature of harmonised standards

While compliance with harmonised standards is not mandatory, their practical effect means that economic operators often adopt them to ensure market access and demonstrate compliance with EU requirements.

Impact of the ruling

The ruling confirmed the legal significance of harmonised standards and their integration into the EU legal framework. The CJEU determined that harmonised standards, developed by European standardisation organisations under a mandate from the European Commission, are considered part of EU law. This implies that the CJEU has jurisdiction to interpret these standards, ensuring uniform application across Member States. The ruling further emphasised the importance of complying with harmonised standards to benefit from a presumption of conformity, allowing products to be placed on the market within the territory of the Union.

The ruling has significant implications for the European Commission, particularly concerning its role in the standardisation process and the legal framework for harmonised standards. The ruling implies that the Commission must ensure the functioning of the system to deliver a standard that complies with the bears aspects of lawmaking, such as transparency, consistency, and legal certainty in the development and application of harmonised standards.

The key impact of the ruling in a nutshell:

1. Legal oversight of the Commission

Harmonised standards are part of EU Law: the ruling clarified that harmonised standards, though developed by private standardisation organisations (CEN, CENELEC and ETSI), are part of EU law when referenced in EU directives or regulations. This subjects them to legal scrutiny by the Commission and the CJEU.

The Commission's responsibility for legal certainty: the Commission is to ensure that harmonised standards are procedurally developed according to EU law and that their content aligns with the essential requirements set out in sectoral secondary legislation.

2. Enhanced transparency in standardisation

Reinforcement of standardisation mandates: the ruling underscored the need for clear and specific mandates from the Commission addressed to standardisation organisations. The Commission defines the object of the standardisation request (essential requirements) more explicitly to ensure that harmonised standards fully meet the intended objectives as set out in secondary sectorial legislation.

3. Focus on the Quality of harmonised standards

Improvement of processes: the Commission sought to improve its processes for reviewing and assessing harmonised standards to avoid legal challenges. This included ensuring that harmonised standards address the essential requirements of secondary sectoral legislation.

4. Commission's central role in standards' development

The ruling highlighted the Commission´s central role in the EU's standardisation system.

5. Steps taken by the Commission

For the European Commission, the James Elliott ruling emphasised the importance of its central role in ensuring that harmonised standards are effectively integrated into the EU legal framework while supporting the internal market legislation. It also highlighted the Commission's responsibility to oversee the standardisation process and ensure compliance with EU principles.

As regards the impacts described above, the ruling stressed the importance of the controls mechanisms, which had already been foreseen by Article 10 and 11 of the Regulation (EU) No 1025/2012. Those articles relate to the *ex ante*, *ex durante* and *ex post* phases of the development of harmonised standards and the central role played by Commission. The Commission did not amend the regulation and opted to enhance the development process of standards to better align with the principles of the rule of law and ensure its effective implementation. Consequently, the Commission revised its templates for standardisation requests, whereby the object of the standardisation request (essential requirements) is explicitly described to ensure that harmonised standards fully meet the intended objectives as set out in secondary sectorial legislation.

Furthermore, the Commission adapted the assessment systems for draft harmonised standards and the practice of final evaluations before taking the decision whether to publish the references of harmonised standards in the OJEU, in view to enhance quality and oversight of standards' development. To streamline the process of evaluating the standards, the Commission concluded a new services contract with HAS (Harmonised Standard Consultants) who assist the Commission in assessing the draft harmonised standards prior to publication of its reference in the OJEU. Finally, the Commission changed the publication method of referencing of harmonised standards in the OJEU. Whereas previously, harmonised standards were cited in the C-series (Communication), today they are referenced in the L-series (Legislation) of the OJEU.

2. Case T-474/15 Global Garden Products Italy SpA (GGP Italy) v European Commission

The ruling of the CJEU on harmonised standards was delivered in case T-474/15 Global Garden Products Italy SpA (GGP Italy) v European Commission on 26 January 2017. The European Commission had decided to withdraw a lawn mower from the market, following a notification by the Latvian authorities, due to alleged non-compliance with the harmonised standard EN 60335-2- 77:2010. Global Garden Products Italy SpA requested this decision be annulled.

Global Garden Products Italy SpA Italia had placed the lawn mower on the market in 2012 based on standard EN 60335-2-77:2006, when this standard was harmonised with the Machinery Directive 98/37/EC, but not automatically with the revised version of the Machinery Directive, Directive 2006/42/EC. The harmonised standard EN 60335-2-77:2010 was published in the OJEU in April 2011, but the Commission never set an expiry date for the previous harmonised standard of 2006, which had been officially withdrawn on 1 September 2013 by the standardisation body.

The issue at stake was thus the validity and legal effect of a harmonised standard which was revised but not withdrawn from the OJEU. More specifically, the question was whether the

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manufacturer, Global Garden Products Italy SpA, could have relied on the standard EN 60335-2-77:2006 in the period between 2012 and 1 September 2013.

In its ruling, the CJEU established that the harmonised standard EN 60335-2-77:2006, having not been formally withdrawn by the Commission, continued to be considered harmonised until its formal withdrawal in 2013.

The key findings of the Court:

1. Legal certainty and harmonised standards:

The CJEU emphasised that the principle of legal certainty is fundamental in EU law, requiring that rules be clear and predictable for those subject to them.

2. Legal effect and harmonised standards:

The CJEU held that the Commission has the power, granted by the Regulation (EU) No 1025/2012, to trigger the legal consequences of a harmonised standard. That includes the power to initiate the legal effect of a harmonised standard and to establish the end of this effect. The means of communicating the temporal aspect of the legal effect, is publication in the OJEU.

Impact of the ruling

The Global Garden ruling reinforced the importance of legal certainty and the proper application of harmonised standards by the European Commission. The ruling highlighted the importance of the following elements for the Commission and the standardisation system:

Adherence to legal certainty:

The Commission must ensure that its decisions respect the principle of legal certainty, particularly by considering the relevant harmonised standards in effect at the time of a product's market entry. This approach prevents retroactive application of standards and ensures fairness for manufacturers.

Consistency in the application of standards:

The ruling underscores the need for the Commission to apply harmonised standards consistently and avoid using updated standards to assess products that were compliant with earlier versions at the time of their placement on the market. Such consistency is vital to provide legal clarity and stability for economic operators.

Steps taken by the Commission following the ruling

The CJEU recognised the exclusive power granted by Regulation (EU) No 1025/2012 to the Commission to initiate the legal effect of a harmonised standard (by means of the publication of its reference in the OJEU) and to end it via an explicit repeal of a harmonised standard. Because of this ruling, the Commission modified the practice by which it publishes the lists of harmonised standards under specific legal acts.

3. CASE C-630/16 ANSTAR OY V TURVALLISUUS- JA KEMIKAALIVIRASTO (TUKES)

The ruling of the CJEU on harmonised standards was delivered in case C-630/16 Anstar Oy v Turvallisuus- ja kemikaalivirasto on 14 December 2017. The case was referred to the CJEU by the Finnish Administrative Court, Helsinki (Helsingin hallinto-oikeus) for a preliminary ruling, requiring the CJEU to provide guidance on the relevant EU law, under Article 267 TFEU. The CJEU clarified the role of standardisation requests (formerly known as 'mandates') in relation to the legal effect of the harmonised standards concerned.

The CJEU stated that "[i]t is necessary […] to interpret a harmonised standard in the light of the mandate from which it originates. […] harmonised standards are to be established by the European standardisation bodies […] on the basis of requests issued by the Commission. […] the Commission must assess the conformity of harmonised standards established by the European standardisation bodies with the relevant mandates". The CJEU concluded that "[i]t follows that the scope of a harmonised standard cannot be interpreted more broadly than that of the mandate on which it is based".

4. CASE C-185/17 MITNITSA VARNA V SAKSA

The ruling of the CJEU (Grand Chamber) on standards was delivered in case C-185/17 SAKSA on 22 February 2018. The case was referred to the CJEU by the Administrative Court, Varna, for a preliminary ruling, requiring the CJEU to provide guidance on the relevant EU law, under Article 267 TFEU.

Standard 'EN 590:2013', which lays down requirements and test methods for marketed automotive diesel fuel and note g to Table 3 specifies that 'EU Common Customs Tariff definition of gas oil may not apply to the grades defined for use in arctic or severe winter climates'. According to the Administrative Court, Varna, definition which must be used as regards the fuel at issue is not clear from that note. The referring court asks whether the Combined Nomenclature must be interpreted as meaning that a mineral oil, such as that at issue in the main proceedings, may be classified as gas oil when it meets the requirements laid down in standard EN 590:2013 relating to gas oil for arctic or severe winter climates. The CJEU clarified the parts of a standard that may be considered to form part of EU law, in light of the reference made to that standard in EU law.

The CJEU stated that "[h]owever, it suffices to note that the reference to standard EN 590:2013, in accordance with footnote 1 to Annex II to Directive 98/70, relates solely to the test methods referred to in that standard. Since note g to Table 3 of standard EN 590:2013 contains no test method, it cannot be considered to form part of EU law and is irrelevant for the purposes of establishing the tariff classification of goods."

5. CASE C-160/20 STICHTING ROOKPREVENTIE JEUGD AND OTHERS V STAATSSECRETARIS VAN VOLKSGEZONDHEID, WELZIJN EN SPORT (STICHTING I)

The ruling of the CJEU (Grand Chamber) on standards was delivered in case C-160/20 Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport on 22 February 2022. The case was referred to the CJEU by the District Court, Rotterdam for a preliminary ruling, requiring the CJEU to provide guidance on the relevant EU law, under Article 267 TFEU.

The case at national level concerned a foundation, Stichting Rookpreventie Jeugd (Youth Smoking Prevention Foundation, Netherlands) and the Nederlandse Voedsel- en Warenautoriteit (Dutch Food and Consumer Product Safety Authority). The former requested an order from the latter that, first, ensures that filter cigarettes offered for sale to consumers in the Netherlands comply, when used as intended, with the maximum emission levels for tar, nicotine and carbon monoxide prescribed by Directive 2014/40/EU and, second, orders manufacturers, importers and distributors of tobacco products to withdraw from the market filter cigarettes allegedly not complying with those emission levels. The request was not granted. During the court proceedings, the plaintiffs submitted that Article 4(1) of Directive 2014/40 does not require recourse to a particular method of measuring emission levels and that it is clear, inter alia, from several studies that another measurement method (the 'Canadian Intense' method) should be applied in order to determine the precise emission levels for filter cigarettes used as intended. The District Court, Rotterdam, made a reference to the CJEU for a preliminary ruling concerning, inter alia, the validity of Article 4(1) of Directive 2014/40, having regard to the principle of transparency, to a number of provisions of EU law and to the World Health Organisation Framework Convention on Tobacco Control.

The key findings of the Court:

1. Direct references to ISO standards in EU law

The CJEU clarified the EU legislators have the discretion to make standards mandatory by referring them in the law ("it is open to the EU legislature to refer, in the acts that it adopts, to technical standards determined by a standards body, such as the International Organisation for Standardisation (ISO)"). The CJEU added that "the principle of legal certainty requires that the references to such standards be clear and precise and predictable in its effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law", thereby excluding the possibility to make generic references to standards in EU law.

2. Principle of legal certainty and transparency

The CJEU analysed the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency. It noted that while that provision refers to ISO standards which have not been published in the OJEU, it does not lay down any restriction concerning access to those standards, including by making that access subject to the submission of a request pursuant to the provisions regarding public access to documents of the Unions' institutions.

Furthermore, the CJEU held that while imposing obligations on legal entities using technical standards which are not available for free is possible, this legislative technique would not be appropriate to impose obligations on citizens and individuals ("it should also be stated that, in accordance with the principle of legal certainty […], technical standards determined by a standards body, such as ISO, and made mandatory by a legislative act of the European Union are binding on the public generally only if they themselves have been published in the Official Journal of the European Union").

As regards the validity of Article 4(1) of Directive 2014/40, having regard to Article 297(1) TFEU, read in light of the principle of legal certainty, the CJEU stated that the EU legislature, in light of the broad discretion that it has in the exercise of the powers conferred on it where its action involve political, economic and social choices and where it is called on to conduct

complex assessments and evaluations, may refer, in the acts that it adopts, to technical standards determined by a standards body, such as the International Organisation for Standardisation (ISO). However, the CJEU pointed out that the principle of legal certainty requires that the reference to such standards be clear and precise and predictable in its effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law. In the present instance, the CJEU held that, since the reference made by Article 4(1) of Directive 2014/40 to the ISO standards complies with that requirement and the directive was published in the OJEU, the mere fact that this provision refers to ISO standards that have not, at this juncture, been so published is not capable of calling the validity of that provision into question.

3. ISO standards and obligations of legal or natural persons

Nevertheless, as regards the ability of ISO standards to bind individuals, the CJEU stated that, in accordance with the principle of legal certainty, such standards made mandatory by a legislative act of the Union are binding on the public generally only if they themselves have been published in the OJEU. In the absence of publication in the OJEU of the standards to which Article 4(1) of Directive 2014/40 refers, the public is thus unable to ascertain the methods of measuring the emission levels prescribed by that directive for cigarettes. On the other hand, regarding the ability of ISO standards to bind undertakings, the CJEU states that, insofar as undertakings have access to the official and authentic version of the standards referred to in Article 4(1) of Directive 2014/40 through the national standards bodies, those standards are binding on them.

Impact of the ruling

The Stichting Rookpreventie Jeugd ruling underscored the importance of legal clarity and transparency when incorporating standards into EU law through direct references in legislation. The CJEU determined that the ISO standards referenced in secondary sectoral legislation may not, in case of absence of their publication in the OJEU, impose legal obligations on individuals. The ruling highlighted the need for the Commission to assess direct referencing of [documents] of third-party standards, such as those from ISO, into EU legislation, were secondary sectoral legislation imposes legal obligations on individuals.

6. Case C-588/21 P Public.Resource.Org and Right to Know v Commission and Others

The ruling of the CJEU (Grand Chamber) on harmonised standards was delivered in case C-588/21 P Public.Resource.Org of 5 March 2024. The ruling concerned an access to documents request submitted under Regulation (EC) No 1049/2001 (Access to Documents Regulation) regarding public access to documents of the EU institutions. Two transparency NGOs ("Public.Resource.Org" and "Right to Know") submitted a request for access to documents of the texts of four harmonised standards. The Commission refused access and the two NGOs appealed the Commission decision denying them access to the documents request (case T-185/19). In first instance, on 14 July 2021, the General Court ruled in favour of the Commission, stating that there was no overriding public interest in the public disclosure of the requested standards and that the intellectual property rights of the ESOs were protected under the Treaties. The NGOs appealed the judgment. The Grand chamber of the Court of Justice held that the Commission erred in not disclosing the four requested harmonised standards under the Access

to Documents Regulation and established that an overriding public interest in disclosure exists, that prevails over the commercial interests of a third party.

The key findings of the Court

1. Harmonised standards are part of EU law

The CJEU underlined that pursuant to Regulation 1049/2001, the EU institutions may refuse access to a document where its disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property, unless there is an overriding public interest in disclosure. The CJEU then recalled that it had already held that a harmonised standard, adopted on the basis of a directive and the references to which have been published in the OJEU, "forms part of EU law owing to its legal effects".

2. Rule of law and transparency of harmonised standards

The CJEU noted that it follows from Article 2 TEU that the European Union is based on the principle of the rule of law, which requires free access to EU law for all natural or legal persons of the EU, and that individuals must be able to ascertain unequivocally what their rights and obligations are. That access must in particular enable any person whom legislation seeks to protect to verify, within the limits permitted by law, that the persons to whom the rules laid down by that law are addressed actually comply with those rules. Accordingly, by the effects conferred on it by EU legislation, a harmonised standard may specify the rights conferred on individuals as well as their obligations, and those specifications may be necessary for them to verify whether a given product or service actually complies with the requirements set out in such legislation. In those circumstances, the CJEU finds that there is an overriding public interest in the disclosure of the requested harmonised standards. Hence, the CJEU concluded that "it must be held that there is an overriding public interest, within the meaning of the last clause of Article 4(2) of Regulation No 1049/2001, justifying the disclosure of the requested harmonised standards". The CJEU thus ordered the Commission to disclose the relevant harmonised standards.

Impact of the ruling

The judgment underscores the importance of the rule of law and the principle of free access to EU law.

Access to harmonised standards

The Commission's refusal to disclose harmonised standards adopted by the European Committee for Standardisation (CEN) to Public.Resource.Org Inc. and Right to Know CLG was overturned. The CJEU ruled that there is an overriding public interest in the disclosure of harmonised standards which form part of EU law. The Commission has an obligation to disclose harmonised standards under Regulation 1049/2001 on access to documents.

Overriding public interest

The CJEU recognised the importance of free access to EU law, as enshrined in Article 2 TEU. This right allows individuals to verify their rights and obligations and to verify compliance with

EU legislation. The Commission must disclose the requested harmonised standards under Regulation 1049/2001 on access to documents.

Disclosure of harmonised standards

Consequently, the Commission discloses harmonised standards pursuant to Regulation 1049/2001.

As regards harmonised standards adopted by the European standardisation organisations CEN and Cenelec: the harmonised standards, which had been disclosed under Regulation 1049/2001, can be freely accessed on the online national readability platforms of the national standardisation bodies in a read-only format. As regards harmonised standards based on ISO or IEC international standards, those are available via individual requests for access to documents, pursuant to Regulation 1049/2001.

As regards harmonised standards adopted by the European standardisation organisation ETSI. harmonised standards, standards and other deliverables adopted by ETSI are available on its website and are freely accessible.

7. CASE C-155/24 NEDERLANDSE VOEDSEL- EN WARENAUTORITEIT AND OTHERS (STICHTING II)

The ruling of the CJEU (Grand Chamber) on standards was delivered in case C-155/24 Nederlandse Voedsel- en Warenautoriteit and Others v Stichting Rookpreventie Jeugd on 21 April 2026. The case was referred to the CJEU by the Supreme Administrative Court for Trade and Industry, Netherlands (College van Beroep voor het bedrijfsleven) for a preliminary ruling, requiring the CJEU to provide guidance on the relevant EU law, under Article 267 TFEU.

In 2018, the Dutch Youth Smoking Prevention Foundation requested the Netherlands Food and Consumer Product Safety Authority (NVWA) to ensure that filter cigarettes in the Netherlands complied with the maximum emission levels for tar, nicotine and carbon monoxide. Those levels are established in Directive 2014/40/EU, which refers to measurement methods laid down in international standards (ISO). The standards have not been published in the OJEU. As the NVWA refused that request, the matter was brought before the Dutch courts. In 2020, District Court, Rotterdam, referred questions to the CJEU for a preliminary ruling on Article 4(1) of the directive. The CJEU replied to those questions by judgment of 22 February 2022 (C-160/24). Following that judgment, District Court, Rotterdam ruled that the ISO standards referred to in Netherlands law are not enforceable against the foundation and that the method for measuring emission levels described in those standards is not consistent with the directive. An appeal was brought against that judgment of District Court, Rotterdam. The Supreme Administrative Court, Netherlands, referred further questions to the CJEU for a preliminary ruling. As regards standards, the question posed by the referring court was whether standards referred to in Directive 2014/40/EU, which have not been published in the OJEU, are enforceable against individuals or only against undertakings.

The key findings of the Court:

1. Rule of law and access to mandatory standards

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The Court found that an individual must have free access to standards rendered mandatory, in compliance with the principle of the rule of law. This means that such access must be general, effective, without charge and non-discriminatory.

2. Intellectual property rights

The Court concluded that it is for the Union to bear the costs associated with creating free access to the official and authentic version of those standards. This applies in particular where those standards are protected by intellectual property rights.

Impact of the ruling:

The Commission must provide access to mandatory standards under a system of access which is general, effective, without charge and non-discriminatory.

ANNEX 15: CASE STUDIES

1. CASE STUDY – CONSTRUCTION

1.1. Context

The construction sector is covered by 445 harmonised standards under the Construction Products Regulation (CPR). Due to the high level of details needed for standardisation requests in the construction industry, the standard development process is systematically lengthy. The drafting of standardisation requests takes on average approximately 1.5 years, while the implementing act procedure may require additional six months[462].

However, a pilot exercise on cement standardisation has shown that the process can be shortened, particularly during the drafting phase. The pilot consisted of prioritising each step of the standard development process by the Commission, CEN, and HAS consultants. In this way, the shortest possible duration for developing a hEN in the construction sector, can be identified. The pilot, which started in July 2025, currently reached the enquiry phase and is expected to lead to publication by July 2027, has demonstrated that the overall process can be reduced to around two years[463].

A further feature of the construction sector concerns European Assessment Documents (EAD), developed by the European Organisation for Technical Assessment (EOTA). These constitute alternative standardisation deliverables for innovative products and are generally developed more quickly than hENs[464]. Such EAD can also be used as a fallback option in case of absence of hENs.

1.2. Baseline

The following main problems were reported in this sector[465]:

1. **Inefficiency of the standard development process**, especially regarding the drafting phase and the number of formal objections, which generate significant delays. At present, the Commission receives the final version of hENs only when they are ready for citation in the OJEU. At that stage, the Commission cannot modify the content and accept the standard subject to such limited amendments or introduce targeted modifications; it can only block the process, i.e. formally reject the hEN and request a revision. This contributes to longer standard-development timelines (see Section 1.3.1).
2. Moreover, CEN reportedly applies internal policies that can significantly delay the process. These policies include multiple checks and approvals, as well as fixed procedures that apply in the same way regardless of the type, size, or complexity of the deliverable. For example, even minor editorial changes may be subject to a minimum processing period of three months, regardless of how limited or simple the amendments are.

[462] Case study interview.
[463] *Ibid.*
[464] *Ibid.*
[465] *Ibid.*

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3. **Shortage of experts involved in standardisation activities**. This is linked to limited funding, time constraints and insufficient resources, which affect the capacity of relevant actors to participate effectively in the process.
4. **Current measures intended to ensure balanced SME representation do not appear to be fully effective**. Participation in technical committees is often concentrated among a limited number of organisations, which may exercise disproportionate influence over the standard-development process.
5. **Standardisation deliverables are not sufficiently digitally friendly**. For instance, standards related to the Digital Product Passport (DPP) may be provided as extensive tables in PDF format. Standardisation requests should therefore include more specific requirements on the format of technical annexes, ensuring that they are provided at least in a machine-readable format (see Section 1.3.3).
6. Concerning the technical content, standards are requested and monitored under the specific responsibility of single units within the Commission and linked to individual regulatory frameworks. This might bring excessive 'gold plating' on businesses (beyond the essential requirements of the legislation) and further harmonisation in approach between Commission services would be required.

1.3. Impact of Policy Options

1.3.1. Increased accountability of ESOs and cooperation with the Commission

Increased cooperation between the Commission and CEN during the drafting phase was perceived to significantly shorten the standard-development process. In particular, if Commission services would systematically review draft standards at the first committee draft, enquiry and formal vote stages, this would help identify, at an earlier stage, errors or inconsistencies that could subsequently prevent citation in the Official Journal of the European Union. This role is currently fulfilled by the HAS Consultants to a certain extent, but this should not exonerate the Commission units from being more directly involved in the development phase of standards. In this way, the Commission could alert the relevant technical committee before the draft is submitted to the formal vote, thus reducing the likelihood of formal objections or requests for revision at a later stage of the process.

1.3.2. Common Specifications

The provisions on Common Specifications set out in Article 8 of the Construction Products Regulation (CPR) establish conditions and criteria for their use as a fall-back option where hENs are not available and the ESOs are unable to deliver.

In the construction sector, alternative measures, such as the use of existing standards, the development of standards by other SDOs, or the introduction of a temporary presumption of conformity based on technical specifications, appear to be of limited applicability. hENs in this sector must reflect the regulatory requirements defined in each Member State's national legislation (contrary to "classic" NLF legislation, where requirements are defined at European level). This makes it difficult for standards developed by other SDOs to provide a suitable alternative that is fully aligned with national regulatory frameworks. Moreover, the use of a temporary presumption of conformity would also be problematic in this sector, as construction products are used in buildings and infrastructure with long life cycles. If the applicable technical requirements were temporary or subsequently replaced, this could create legal uncertainty and

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practical difficulties for manufacturers, users and public authorities, and could potentially have implications for public safety.

In this context, and potentially also in other sectors characterised by long product life cycles, Common Specifications provide a useful last-resort instrument in exceptional cases where ESOs cannot deliver, or where standardisation work is blocked within technical committees. However, given that there have already been instances in which ESOs were unable to deliver on a standardisation request, interviewees indicated the need for a more horizontal fallback option, such as the EAD developed by EOTA.

1.3.3. Digitalisation of the standard-development process

As noted above, in some cases standards in the construction sector are delivered as extensive tables in PDF format. This format was considered by interviewees to be obsolete and not sufficiently suitable for digital use. The introduction of a requirement to provide deliverables in a machine-readable format, at least for technical annexes, was therefore considered useful. The need to digitalise standardisation processes was also highlighted in some contributions to the targeted survey by respondents operating under the Construction Products Regulation. Digitalisation was considered to have potential to improve the efficiency, traceability and accessibility of standards, while facilitating their integration with emerging tools such as Digital Product Passports. It could also help reduce the administrative burden on SMEs in the construction industry, without undermining the quality of standards[466].

1.3.4. Binding legal obligations on NSBs for involvement of SMEs revising the provisions in Art. 6

The results of the targeted survey suggest that introducing binding legal obligations on NSBs for involvement of SMEs (i.e. revising the provisions in Art. 6) could be effective in the construction industry. However, further education and training on standardisation are needed to ensure that SMEs well understand the added value of their participation and are more willing to participate proactively in standardisation activities[467].

1.3.5. One product, one standard

The application of a "one product, one standard" principle could help reduce administrative burden for businesses by avoiding overlapping or duplicative standardisation requirements for products falling under the scope of more than one EU legal act. This approach happens already now in some sectors but could be introduced more broadly through either amendments to the Standardisation Regulation, or the implementation of the Digital Product Passport. A relevant best practice is the development of the EN 16510-2-X series, which was designed to support both the Ecodesign Regulation and the Construction Products Regulation[468].

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[466] Targeted survey sent to industry and companies, sorted by companies dealing with harmonised standards under the Regulation CPR/CPD (*Q16: Please elaborate on your response above, if necessary*).
[467] Targeted survey sent to industry and companies, sorted by companies dealing with harmonised standards under the Regulation CPR/CPD (*Q33: To what extent do you think that these measures will support the achievement of the objective to improve inclusiveness and involvement in the standardisation processes?*).
[468] Case study interview.

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2. CASE STUDY – ARTIFICIAL INTELLIGENCE

2.1. Context

The AI Act (Regulation 2024/1689) has set out legal rules for AI systems, complemented by other regulatory instruments as guidelines, code of practice, harmonised standards, and common specifications. Within this regulatory framework, hENs play a pivotal role in operationalising the requirements for high-risk AI systems laid down in Section 2 of the AI Act (Articles 8 to 15).

In the AI Act, Art. 40 lays down the normative foundation for harmonised standards and the presumption of conformity regarding high-risk AI systems, stating that "*High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter*".

In May 2023, the European Commission issued a standardisation request to CEN and CENELEC that led to the establishment of the Joint Technical Committee 21 (JTC 21) for the execution of the requested standardisation work. The committee comprises 5 working groups (WGs) carrying out standardisation activities covering the requirements for AI high risk systems laid down in Section 2 (data governance, cybersecurity, risk management, etc..)[469].

In addition to WG1 "Strategic Advisory", tasked with monitoring AI developments and coordinating crosscutting issues across JTC 21, the remaining WGs are developing the following standards:

Working Group 2 - Operational aspects

- Conformity Assessment
- Quality Management Systems
- Risk Management

Working Group 3 – Engineering aspects

- Quality and governance of datasets
- Managing bias
- Evaluation methods for accurate computer vision systems
- Natural Language Processing
- Logging

Working Group 4 – Foundational and societal aspects

- AI trustworthiness framework: logging, transparency and human oversight
- AI trustworthiness framework: accuracy and robustness

[469] EU Commission - Standardisation request M/593 - 22 May 2023 eNorm Platform

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- Cybersecurity specifications for AI systems

Although the European Commission initially set an April 2025 deadline for standards development, JTC 21's work has progressed considerably slower than anticipated, with first drafts only expected by late 2026. This created a critical misalignment: the high-risk obligations under the AI Act were set to apply from 2 August 2026 for Annex III systems and 2 August 2027 for Annex I systems (Article 113 AI Act) — where Annex I covers product-specific risks (machinery, medical devices, aviation, automotive, etc.) and Annex III covers use case-specific risks (critical infrastructure, education, access to essential services, etc.)[470].

The most relevant AI standards at international level are developed by ISO/IEC SC 42, the primary body developing AI standards with global reach, e.g. ISO/IEC 42001 on AI management systems, which has gained significant industry traction. Other standards and technical specifications were developed by non-international bodies such as the National Institute of Standards and Technology (NIST)[471] - in particular the AI Risk Management Framework, NIST AI 100-1 - and the Institute of Electrical and Electronics Engineers (IEEE), notably the IEEE 7000 series, addressing ethical considerations in the design of autonomous and intelligent systems.

In the AI domain, however, the automatic transposition of international standards into European harmonised standards is not straightforward. Many aspects of the AI Act require standards that go beyond what existing ISO/IEC work provides, particularly as regards the protection of fundamental rights and the management of societal impacts — dimensions that are not central to the ISO/IEC framework. As a result, JTC 21 is expected to adopt existing ISO/IEC standards where they are consistent with EU values and the AI Act's objectives, while the remaining gaps — which in the AI context are substantial — will be filled by new standards developed autonomously at European level.

2.2. Baseline

The development of harmonised standards under JTC 21 has gone slower than planned. Evidence from stakeholder interviews consistently identifies a structural shortage of professionals combining deep AI technical knowledge with standardisation process expertise as the primary bottleneck. Working groups frequently lack the experts needed to advance drafts swiftly, and the complexity of AI subject matter means that onboarding new participants is time-consuming and costly. Delayed and insufficiently detailed feedback from the European Commission on interim deliverables has further extended timelines, with substantial

[470] The Digital Omnibus proposal, published by the European Commission on 19 November 2025 and still pending adoption, seeks to address this gap by conditioning the entry into force of high-risk obligations on the prior availability of harmonised standards and Commission guidelines. Once the Commission confirms their availability, a transition period of six months would apply for Annex III systems and twelve months for Annex I systems, with absolute backstop dates of 2 December 2027 and 2 August 2028 respectively. However, so far, the second political trilogue held on 28 April 2026 ended without agreement, leaving the original deadline of 2 August 2026 legally in force.

[471] NIST is a public agency of the United States Department of Commerce. At its foundation in 1901 until 1988, the agency was named the National Bureau of Standards. Therefore, the standards and technical specifications developed by NIST are considered as American national standardisation deliverables.

consequences in a sector where early technical choices carry direct regulatory implications under the AI Act.

2.3. Impact of Policy Options

2.3.1. Temporary Presumption of Conformity for standardisation deliverables other than harmonised standards

The proposal for 'rolling publication' of standards from 30–40% completion was viewed as particularly impactful: early release would allow industry — especially SMEs and innovators — to begin aligning development pipelines with the likely direction of requirements, while also generating informed feedback that improves the final standard.

2.3.2. Improved EU coordination of EU Member States position and experts' participation in international standardisation organisation

Interviewees called for structural improvements to EU coordination ahead of international meetings, including stronger obligations on ESOs and national standardisation bodies to align European positions before engaging in ISO/IEC fora. Findings from interviews point to a structural weakness in the EU's participation in ISO/IEC JTC 1/SC 42[472]. European experts generally fail to coordinate their positions before and during international meetings: delegates from different Member States, companies, and NSBs/NCs have frequently presented divergent or competing views. The result is a fragmented European presence that undermines the EU's collective influence in international AI standardisation at a stage where foundational technical choices are still being made.

3. CASE STUDY - ELECTRIC VEHICLE CHARGING INFRASTRUCTURES

3.1. Context

The present case study considers two diverse standardisation development processes that illustrate potential benefits generated by some of the policy options. In particular, it analyses two standardisation processes enabling interoperable communication in the electric vehicle recharging ecosystem implemented under **standardisation request M/581** of 24.3.2022[473], i.e. **IEC 63110** and **IEC 63119**. Despite the European Commission initially setting December 2023 as a deadline for adoption of these standards by the ESOs, the standardisation development

[472] The ISO/IEC Joint Technical Committee 1, and particularly its Sub-Committee (SC) 42, is the technical body primarily tasked with developing international standards for AI. It is currently coordinated by the American national standardisation body ANSI, which holds the secretariat position of the SC. Out of 56 participating national members in that SC, 20 are EU NSBs.

[473] Table 5: List of new European standards supporting interoperable communication in the electric vehicle recharging ecosystem, Commission Implementing Decision on a standardisation request to the European standardisation organisations as regards communication exchange, electricity and hydrogen supply for road, maritime transport and inland navigation in support of Directive 2014/94/EU and its planned revision under the 'Fit for 55' package, available at: Register of Commission Documents - C(2022)1710

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processes experienced delays, thus making it necessary to consider a possible amendment of M/581[474].

The Commission requested European standards for alternative fuel infrastructures across transport sectors, including the EV charging system. One of the key domains to be addressed was the interface enabling communication between charging stations, mobility service providers and e-roaming platforms. The protocol covering this communication is called *Open Charge Point Interface* (OCPI), now managed and reviewed by the EV Roaming Foundation, an industry association. In parallel, an existing IEC standard (IEC 63119) was already under development; two thirds of technical committee experts were not from EU countries. The resulting architecture did not reflect the European ecosystem and market configuration, leading European stakeholders to disengage from the process. The incompatibility of the IEC standard with EU requirements was determined through a detailed technical assessment, conducted by the Electro-Mobility Coordination Group of CEN-CENELEC, together with EU stakeholders and technical experts. Consequently, it was decided to develop a European standard at CEN-CENELEC level first, rather than relying on IEC.

This derogation from the 'international first' principle allowed the ESS to be more responsive to key EU requirements. In a related case, the EU supported the convergence of the Open Charge Point Protocol (OCPP) developed by another EU industry association (Open Charge Alliance / OCA) into the formal standardisation system – ultimately adopted as IEC 63584, instead of the previous IEC 63100 that did not obtain consensus among EU market participants.

IEC 63110

Under standardisation request M/581, the Commission asked CENELEC to establish an EV charging standard by December 2023, with the purpose of creating a single, interoperable communication solution between the charging point and the back-end system of the recharging point's operator[475].

At international level, this communication solution was based on an international protocol called **Open Charge Point Protocol (OCPP)**, developed and maintained by the Open Charge Alliance (OCA)[476], which was already widely deployed across Europe. In parallel, an existing IEC standard (IEC 63110) was also being developed[477]. The Commission identified IEC 63110 as the baseline for the development of the European standard, while accounting for the OCPP.

1. [474] Commission Implementing Decision on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence - Register of Commission Documents - C(2023)3215.

[475] Commission Implementing Decision on a standardisation request to the European standardisation organisations as regards communication exchange, electricity and hydrogen supply for road, maritime transport and inland navigation in support of Directive 2014/94/EU and its planned revision under the 'Fit for 55' package, available at: Register of Commission Documents - C(2022)1710

[476] Open Charge Alliance (OCA) is a non-profit organisation of EV charging hardware and software vendors and charging network operators and service providers. Further information is available at: Open Charge Alliance - Connecting the EV charging industry.

[477] Evidence from stakeholder interviews.

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Nevertheless, due to the slow pace of the standardisation development process within IEC, industry stakeholders endorsed the **adoption of the OCPP over the IEC 63110**[478]. Many OCA members were part of the IEC Technical Committee TC 69 developing IEC 63110 and expressed a clear preference for OCPP which was already consistent with the EU market needs[479]. As a result, in mid-2023, the IEC Standards Management Board discontinued the work on IEC 63110[480], and the IEC and OCA agreed to propose adopting OCPP as an IEC International Standard. As a consequence, OCA requested to become Liaison to IEC Technical Committee TC 69 and submitted, via the IEC Fast Track procedure, the OCPP2.0.1 version for its approval.

Finally, by late 2024, the **IEC published the IEC 63584** (i.e., OCPP2.0.1ed3) as international standard and, in January 2025, CENELEC adopted the **EN IEC 63548**[481].

3.1.1.1.Baseline

The development of EN IEC 63548 has proved to be significantly slower than the deadline set by the EC's standardisation request[482]. The excessive slowness of the standardisation process has *de facto* weakened the IEC work and the smooth function of the ESS[483]. Moreover, evidence from stakeholder interviews also outlined two main related issues, in particular a lack of transparent **governance within OCA**, and the absence of a meaningful **participation of Annex III and NSBs** in the fast-tracked procedure[484], creating an inclusiveness gap for EU stakeholders.

3.1.1.2.Impact of Policy Options

This case shows that ***market players tend to prefer agile solutions when the ESS or international standardisation organisations are not up to speed***. Based on this case study, among the policy options envisaged under the revision of Regulation 1025/2012, **Measure 1.2. (*Better leveraging existing standards and technical specifications from alternative SDOs through the ESOs)*** may be a useful measure to better meet the market players' needs and to make the ESS more responsive to the market pace. Through this measure, the Commission and market players could benefit from a timelier starting point, while respecting EU principles.

Furthermore, in the targeted survey to industry organisations and companies, **72% of respondents** (18 out of 25 involved in technical committees for standardisation of electric vehicle charging infrastructure) agreed with the option of ***using of existing standards and technical specifications when the ESOs cannot deliver***, to streamline and accelerate the development of high-quality standards within the ESS.[485]

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[478] Evidence from stakeholder interviews.
[479] Evidence from stakeholder interviews.
[480] OCA, OCPP Chronicles 2009 – 2025, available at: OCPP-Chronicles-2009-2025.pdf
[481] OCA, OCPP Chronicles 2009 – 2025, available at: OCPP-Chronicles-2009-2025.pdf
[482] Evidence from stakeholder interviews.
[483] Evidence from stakeholder interviews
[484] Evidence from stakeholder interviews
[485] Targeted survey to industry organisations and companies: Q19 To what extent do you believe that these measures will support achieving the objective of simplifying and accelerating the development of high-quality standards? When the ESOs cannot deliver, use of existing standards. Sample size, N = 25

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3.1.2. IEC 63119

Under standardisation request M/581, the European Commission requested CEN and CENELEC to develop a European standard on information exchange for electric vehicle charging e-roaming service by December 2023. The standard should enable charging stations of different providers to exchange information across EU Member States, and to define technical specifications to create harmonised peer to peer communication between market parties and electric vehicle clearing houses.[486]

At international level, the **Open Charge Point Interface (OCPI)**, developed by the EV Roaming Foundation[487], was the primary protocol governing this communication. In tandem, an IEC standard (IEC 63119) was already being developed to cover this domain. Despite this on-going effort under the IEC, European stakeholders withdrew from this international standardisation process as it was considered unsuitable to the European market needs and overall EU ecosystem. This was mainly due to the dominant participation of non-EU experts in the IEC committee, as two thirds of the technical committee members were coming from non-EU countries. The mismatch between the IEC standard and the European market architecture was also stated in a detailed technical assessment carried out by the Electro-Mobility Coordination Group of CEN-CENELEC, together with European stakeholders and technical experts.

Therefore, with the objective to prioritise a robust European solution, the preferred approach was to develop the standard at **CEN-CENELEC level first, instead of adopting the IEC one**. To coordinate the CEN-CENELEC committees' work with the international landscape, the EV Roaming Foundation agreed to submit its technical specifications for discussion.

3.1.2.1.Baseline

This standardisation development process has represented a case whereby, despite the IEC was developing an international standard (i.e., IEC 63119), CENELEC has initiated their own standardisation process, in derogation from the Frankfurt agreement. This path enabled ESOs to ensure greater consistency between the hEN and the European legislative and market needs.

3.1.2.2.Impact of Policy Options

The case of IEC 63119 has demonstrated that the derogation from the 'international first' principles could support the ESS to deliver a hEN that better aligns with the EU legislation and market structure. This case study reveals that **Measure 2.5 (*Possibility to derogate from the 'international first' principle when ESOs agreement with international standardisation organisations challenge European strategic and sovereignty interests)*** may contribute to the objective of fostering the EU's position in international standardisation.

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[486] COMMISSION IMPLEMENTING DECISION on a standardisation request to the European standardisation organisations as regards communication exchange, electricity and hydrogen supply for road, maritime transport and inland navigation in support of Directive 2014/94/EU and its planned revision under the 'Fit for 55' package, available at: Register of Commission Documents - C(2022)1710

[487] EV Roaming Foundation is a Dutch industry association specialised in roaming services for charging electric vehicles. Further information is available at: About us - evRoaming4EU

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4 CASE STUDY – CRITICAL SPACE TECHNOLOGY

4.1 Context

The EU Space Programme Regulation (Regulation 2021/696)[488] has established a comprehensive framework for European space activities, complemented by sectoral technical instruments including guidelines and standards. Within this regulatory ecosystem, harmonised standards are absent: unlike other sectors governed by the New Legislative Framework (NLF), no harmonised European standards for critical space technologies have ever been developed under Regulation 1025/2012 with references published in the Official Journal of the European Union.

The closest operational approximation to a structured European standardisation effort in this domain dates back to Mandate M/496, through which the European Commission requested CEN, CENELEC and ETSI to develop European standards for the space industry. In response, CEN-CLC/JTC 5 "Space" was established in 2011, producing the EN 16600–16603 series through the transposition of standards developed by the European Cooperation for Space Standardisation (ECSS). However, these European standards carry no presumption of conformity effect.

The most relevant technical standards at European sectoral level are those maintained by ECSS — a collaboration between ESA, Eurospace, and national space agencies — which counts 139 active standards covering project management, engineering, and product assurance. At international level, the primary body is the sub-committee ISO/TC 20/SC 14 (Space Systems and Operations), whose secretariat is effectively held by the American Institute of Aeronautics and Astronautics (AIAA) via ANSI (formally holding the secretariat), with over 110 active projects. Space data and information transfer standardisation is conducted by the other sub-committee ISO/TC 20/SC 13 (where the secretariat is also held by ANSI) in close partnership with the Consultative Committee for Space Data Systems (CCSDS), a body in which the US retains structural influence through NASA's secretariat role.

4.2 Baseline

Evidence from the stakeholder interview and desk research consistently identifies two structural problems: (i) ESOs lack the in-house competence to develop standards for upstream space technologies; (ii) the transposition of existing ECSS standards into EN has not been effective.

4.3 Impact of Policy Options

Among the policy options envisaged under the revision of Regulation 1025/2012, interviewees identify measures regarding Objective 1 and Objective 3 as the most interesting areas where intervention is needed.

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[488] Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013 and (EU) No 377/2014 and Decision No 541/2014/EU

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Regarding Objective 1 — *"Increase Responsiveness"* — the interviewees supported measures under PO 2 and PO 3 that would allow standardisation requests to be directed to organisations other than ESOs. In the absence of a competent ESO for upstream space technologies, interviewees argued that enabling external organisations or consortia to develop standards through open procurement could fill the existing gap. Support was expressed for Measure 2.1: *"ESOs retain pre-emption rights but the Commission can send Standardisation Requests to other SDOs in pre-defined cases, and possibility to use and reference standards from other SDOs"*, provided that institutional preference does not override competence as the primary selection criterion.

Regarding Objective 3 — *"Increase EU Global Relevance"* — interviewees noted that the EU's diminishing position in international space standardisation is directly measurable: European companies are compelled to adopt non-EU technical frameworks to access international markets, at significant cost to technological sovereignty. The ratio of EU versus non-EU standards referenced in procurement activities for EU space missions — such as Copernicus — was identified as a concrete indicator of this dependency. Interviewees also raised the question of restricted, EU-27-only configurations for standard development in sensitive and security-critical domains, arguing that derogation from the Vienna and Frankfurt Agreements and from the current internal rules of the ESOs concerning participation in technical work would be justified in exceptional circumstances where EU strategic interests are at stake.

5. CASE STUDY – ADDITIVE MANUFACTURING

5.1 Context

Additive manufacturing (AM) is a strategic and rapidly expanding market, representing one of the 75 product categories in the machinery sector. AM technologies have known a sharp increase of international patent families (IPFs) since 2013, registering an annual compound growth rate of 26% in the period 2013-2020[489]. However, despite the existence of more than 800 harmonised European standards under the Machinery Regulation, **no AM-specific hENs have yet been developed or cited in the Official Journal of the European Union, and none currently confers a presumption of conformity at EU level**. At international level, the United States have developed a strong position in AM standardisation, notably through ASTM International and its interaction with ISO standardisation activities[490].

5.2 Baseline

Interviewees identified several challenges affecting additive manufacturing standardisation:

- **Difficulties in maintaining the EU's global relevance in AM standardisation**, including by ensuring continued European leadership in the ISO secretariat responsible for additive manufacturing.
- **EU-level coordination and strategic orientation** were less developed than the approach pursued by the United States in AM standardisation.

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[489] EPO, *Innovation trends in additive manufacturing*, 2023, https://link.epo.org/web/service-support/publications/en-additive-manufacturing-study-2023-full-study.pdf

[490] Case study interview.

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- **Limited attention to AM within the Commission**, due to the large number of hENs in the machinery industry already cited and requiring policy oversight. Consequently, the needed focus on AM industry – which is not relevant for the Machinery Regulation – passes at a second stage with respect to more general requirements (see next bullet point).
- **Focus of hENs on the legislative health and safety requirements does not fully address the broader standardisation needs of the AM sector**. According to interviewees, existing machinery standards already cover many relevant health and safety aspects, while other AM-specific issues, such as materials, processes and performance requirements, may be more relevant for innovation and global competitiveness. In this context, interviewees noted that, historically, US industry was more focused on plastic-based AM applications, whereas European industry had a stronger position in metal-based AM applications.
- **Insufficient funding for pre-normative research**, which may contribute to a stronger influence of US-led research and standardisation activities. EU funding of pre-normative work was reported to be significantly lower compared to US standardisation, and increased allocation of resources should be taken into account in the Annual Union Work Programme.
- Efficiency concerns linked to the full overlap between the relevant CEN and ISO technical committees on AM, although both committees were described as active and well organised.
- **Challenges related to dual-use applications**, in particular the limited integration of defence capability needs and the need to ensure greater coherence between civil, defence and dual-use AM standardisation requirements[491].

5.3 Impact of policy options

3.1.3. Common specifications

As additive manufacturing falls within the scope of the Machinery Regulation, it is also covered by Article 20, which sets out the conditions for the use of common specifications. While common specifications have not yet been used under the Machinery Regulation, **interviewees supported the establishment of clear criteria and conditions determining when Commission intervention may be justified**. At the same time, interviewees stressed that common specifications should remain a mechanism of last resort and should not replace the primary role of hENs developed through the ESS.

3.1.4. Pre-normative work funding and ecosystem

Interviewees highlighted the importance of increasing funding for pre-normative work, given the significant gap compared with the US system, playing a leading role in AM standardisation. This necessity has also been highlighted by respondents to the targeted survey who are part of the AM technical committee[492]. In addition, **interviewees supported stronger professional recognition for contributors to standardisation activities**. Measures such as

[491] Case study interview.
[492] Targeted survey sent to industry and companies, sorted by organisations attending the AM technical committee (*Q50: Please elaborate on your response above, if necessary*).

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acknowledging the names of developers in standards, increasing the visibility of standardisation outputs, introducing awards for excellence to showcase high-quality deliverables, and creating regular opportunities for exchange between researchers, SMEs, industry, standardisation organisations and public authorities were considered likely to incentivise greater participation by the research community in standardisation activities[493].

The International Technical Conference on the Enhanced Safety of Vehicles (ESV), which regularly brings together researchers, experts and industry representatives to exchange on and recognise advances in vehicle safety, was cited as a possible benchmark for fostering similar sector-specific communities within European standardisation[494].

[493] Case study interviews.
[494] *Ibid*.