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EVALUATION

of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation

{SWD(2025) 171 final}

Table of contents

1. INTRODUCTION 5
1.1. Purpose and scope of the evaluation 5
2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION? 8
2.1. Description of the intervention and its objectives 8
2.1.1. How does the intervention fit in the wider policy framework? 8
2.1.2. How does the intervention fit in the European standardisation system? 10
2.1.3. Intervention logic 12
2.2. Point(s) of comparison 15
2.2.1 The problems and their expected evolution 16
2.2.2 Monitoring exercises on the implementation of the Regulation 16
3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD? 17
3.1. Implementation of the Regulation 17
3.1.1. Standardisation process: duration and prioritisation 17
3.1.2. Stakeholder representation, inclusiveness, transparency and funding 21
3.1.3. ICT specifications 24
3.2. Evolving standardisation needs 24
4. EVALUATION FINDINGS 26
4.1. To what extent was the intervention successful and why? 26
4.1.1. Effectiveness 26
4.1.2. Efficiency 40
4.1.3. Coherence 55
4.2. How did the EU intervention make a difference and to whom? (EU added value) 58
4.3. Is the intervention still relevant? 59
5. CONCLUSIONS AND LESSONS LEARNED 65
5.1. Conclusions 65
5.2. Lessons learned 68
ANNEX I: PROCEDURAL INFORMATION 70
ANNEX II: METHODOLOGY AND ANALYTICAL MODELS USED 81
ANNEX III: EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS 103
ANNEX IV: OVERVIEW OF BENEFITS AND COSTS AND TABLE ON SIMPLIFICATION AND BURDEN REDUCTION 126
ANNEX V: SYNOPSIS REPORT OF THE STAKEHOLDER CONSULTATION 137
ANNEX VI: FUNDING PROVIDED TO THE EUROPEAN STANDARDISATION ORGANISATIONS 172
ANNEX VII: MINUTES OF THE ACADEMIC EXPERT WORKSHOP 173
ANNEX VIII: BACKGROUND INFORMATION – KEY ELEMENTS OF REGULATION (EU) NO 1025/2012 175
ANNEX IX: BACKGROUND INFORMATION – RELEVANT JURISPRUDENCE ADDRESSING PROVISIONS OF REGULATION (EU) 1025/2012 179
ANNEX X: BACKGROUND INFORMATION – COMPARISON BETWEEN THE EU, CHINESE, JAPANESE AND UNITED STATES' APPROACH TO STANDARDISATION FOR PUBLIC POLICY PURPOSES 187

Glossary

Term or acronym	*Meaning or definition*
AFNOR	French Standardisation Association
AI	Artificial intelligence
ANEC	European Association for the Coordination of Consumer Representation in Standardisation
AUWP	Annual Union Work Programme
BT	Technical board
CCMC	CEN-CENELEC Management Centre
CEN	European Committee for Standardisation
CENELEC	European Electrotechnical Committee for Standardisation
CEPT	European Conference of Postal and Telecommunications Administrations
CJEU	Court of Justice of the European Union
CSRD	Corporate Sustainability Reporting Directive
DPOs	Disabled persons organisations
DSA	Digital Service Act
ECJ	European Court of Justice
ECOS	Environmental Coalition on Standards
EEA	European Economic Area
EFRAG	European Financial Reporting Advisory Group
EFTA	European Free Trade Association
EN	European standard
EQ	Evaluation question
ESO	European Standardisation Organisation
ESS	European standardisation system
ETSI	European Telecommunications Standards Institute

ETUC	European Trade Union Confederation
F4F	FIT for Future Platform
FPAs	Framework partnership agreements
FwC	Framework contract
GA	General assembly
HAS Consultants	Harmonised standards assessment consultants
hEN	Harmonised standard
HLF	High-Level Forum on European Standardisation
ICT	Information and communication technologies
IEC	International Electrotechnical Commission
IETF	Internet Engineering Task Force
IoT	Internet of things
IPR	Intellectual property rights
ISB	International standardisation body
ISO	International Organization for Standardization
JIS	Joint Initiative on Standardisation
JRC	Joint Research Centre of the European Commission
JTC	Joint technical committee
MPEG	Moving Picture Experts Group
MSP	Multi-stakeholder platform on ICT standardisation
NCs	National committees
NGOs	Non-governmental organisations
NLF	New Legislative Framework
NSB	National standardisation body
NSC	National standardisation committee
NSO	National standards organisation

OASIS	Organization for the Advancement of Structured Information Standards
OGs	Operating grants
OJEU	Official Journal of the European Union
OSS	Open-source software
PC	Public consultation
PPE	Personal protective equipment
REACH	Registration, evaluation, authorisation and restriction of chemicals
RMs	Reference materials
SBS	Small Business Standards
SC	Sub-committee
SDGs	Sustainable Development Goals
SME	Small and medium-sized enterprise
SR	Standardisation request
TB	Technical body
TC	Technical committee
TFEU	Treaty on the Functioning of the European Union
UAS	Unmanned aircraft systems
W3C	World Wide Web Consortium
WG	Working group
WTO	World Trade Organization

1. INTRODUCTION

1.1. Purpose and scope of the evaluation

On 1 January 2013, Regulation (EU) No 1025/2012 on European standardisation became applicable, creating a legal basis for using European standardisation as a policy tool to support EU legislation and policies, for products and for services.

Background and context

The Regulation builds on previous EU legislative approaches and instruments. Initially, the traditional legislative approach for the completion of the internal market – referred to as the 'Old Approach' – aimed to harmonise legislation at EU level with detailed texts containing all the necessary technical and administrative requirements for products. However, this approach had shortcomings, leading to the development of the 'New Approach' in 1985. The New Approach restricted the content of legislation to 'essential requirements', leaving the technical details to European harmonised standards. This, in turn, led to the development of European standardisation policy to support this legislation.

The 'New Legislative Framework', adopted in July 2008, built on the New Approach and completed the overall legislative framework. In this context, Regulation (EU) No 1025/2012 provides the rule book for the functioning of the public-private partnership between the European Commission, the European standardisation organisations (ESOs) and national standardisation bodies (NSBs), and stakeholders, institutionalising part of the European Standardisation activities.

Objectives and scope of the Regulation

The Regulation leverages parts of the broader European standardisation system, which is a private, independently operating system that predates the Regulation by many decades. National standardisation organisations have been in operation since the beginning of the 20th century[1]. The three European standardisation organisations, CEN, CENELEC and ETSI, were founded by stakeholders in 1961, 1973 and 1988 respectively to develop market driven consensus based voluntary standards. Organised within these three organisations, stakeholders produce thousands of European standards as technical guidebooks on products, services and processes.

Regulation (EU) No 1025/2012 organises the legal interface between the Commission and the European standardisation system regarding standards requested in support of EU law and policies. The primary focus of the Regulation is the delivery of harmonised standards, defined as a 'European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation'[2].

What is unique about this legal framework is that the Commission specifically asks for the development of harmonised standards in support of EU law and policies 'ex-ante', instead of

[1] For instance, the national standardisation bodies DIN in Germany and AFNOR in France were founded in 1917 and 1926, respectively.
[2] Regulation (EU) No 1025/2012, Article 2(1)(c).

picking and choosing from available technical standards. For this purpose, it establishes rules on the drawing up of European standards and European standardisation deliverables for products and services, the financing of European standardisation, and stakeholder participation. In addition, it sets rules on identifying ICT technical specifications that may be developed by other standard-development organisations, notably to enable their referencing in public procurement.

The work on harmonised standards constitutes only a small part of the overall activities of the European standardisation system. Today, approximately 11% of all standardisation deliverables developed in Europe by the three ESOs follow a public mandate from the European Commission.

Objectives of the evaluation

The main purpose of this evaluation is to present an informed analysis of the current performance of Regulation (EU) No 1025/2012 in relation to the objectives set out in the 2011 standardisation strategy[3] as follows:

(1) European standards need to be developed faster (speed of standard-setting process), reaping the benefits of ICT;
(2) European standards should help improve competitiveness for European businesses;
(3) The capacity of the European standardisation system should be sufficient for the future increased policy-making and legislation needs;
(4) European stakeholders, including small and medium-sized enterprises (SMEs), societal stakeholders[4] and public authorities, should play a greater part in the European and international standardisation processes;
(5) Standards should support the competitiveness of European businesses in the global market, allowing them to access foreign markets and establish business partnerships around the globe.

Since the entry into force of the Regulation, the landscape of European standardisation has changed significantly. New challenges have emerged, in particular a changed geopolitical context, rapid technological development for the green and digital transition, and the need to strengthen education and skills in standardisation. In this context, the Regulation needs to take full advantage of the potential of European standardisation in order to support a resilient, green and digital EU single market and regain global leadership in standardisation processes[5].

The evaluation assesses the **effectiveness, coherence, efficiency, EU added value and relevance** of Regulation (EU) No 1025/2012 against the objectives defined in 2011, while taking into account the changes in the wider standardisation landscape.

Although the focus of the evaluation is retrospective, a forward-looking dimension cannot be completely dismissed to assess the relevance of the Regulation and its fitness for purpose. The evaluation considers the ongoing regulatory developments serving the green and digital agenda.

The Court of Justice of the European Union (CJEU) has been instrumental in shaping the EU's standardisation landscape through its rulings. These judgments have provided valuable insights into the interpretation of provisions governing standardisation in the EU. In recent years, the CJEU has demonstrated an evolving approach to interpreting these provisions, driven by the need

[3] COM(2011) 311 final.
[4] Societal stakeholders are defined in recital 17 of Regulation (EU) No 1025/2012 as "organisations and parties representing interests of greater societal relevance, for instance environmental, consumer interests or employee interests".
[5] COM(2022) 31 final.

to balance competing interests, such as transparency, consumer protection, and a level playing field.

The CJEU's interpretation of provisions in EU standardisation has had significant implications for EU standardisation. For instance, the Court's ruling in *James Elliott Construction* Ltd *v Irish Asphalt Ltd* (C-613/14) clarified that harmonised standards form part of EU law, while the judgment in *Public.Resource.org and Right to Know v Commission* (C-588/21P) indicated that natural or legal persons needed to have access to harmonised standards due to overriding public interests, such as rule of law and transparency.

Scope of the evaluation

While acknowledging the horizontal nature of the Regulation and its role in the implementation of EU harmonised sectoral legislation, the material scope of the evaluation is limited to the Regulation itself.

The evaluation does not cover the amendments[6]. In line with the scope of the Regulation, the evaluation focuses primarily on the delivery of harmonised standards developed for EU policy or legislative needs. Provisions of the Regulation not related to harmonised standards concern ICT technical specifications, which are covered in dedicated sections of this document.

Throughout this document, the term 'European standardisation system' refers to the system of ESOs, national standardisation bodies and stakeholders developing a wide variety of standards and specifications (beyond harmonised standards). This document does not constitute an evaluation of the entire, privately-run European standardisation system but only assesses the aspects, relating to the delivery of standards for EU policy or legislative needs

The evaluation is limited in its geographical scope to EU Member States and EEA countries. The evaluation takes into account that the Regulation allows for EU financing to be used by ESOs for international cooperation, although it is up to the ESOs to decide how to deliver best on the objectives defined in EU grants funded through the Regulation and the single market programme (SMP).

The timeline covers the period from 1 January 2013 (the date of applicability of the Regulation) to 1 January 2023 (scope of the supporting evaluation study), extended to 31 August 2024 where data is readily available.

Methodological approach

This staff working document builds on the accompanying evaluation study that was carried out for the European Commission (DG GROW) and written by Intellera Consulting, Fraunhofer ISI and Trinomics B.V.[7]. The study was conducted using a number of different research tools that allowed for verification and cross-checking of the evidence in accordance with triangulation principles.

[6] 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 (Text with EEA relevance), OJ L 323, 19.12.2022

[7] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Final Report, written by Intellera Consulting, Fraunhofer ISI and Trinomics B.V.

The study relied on the following methods: preliminary desk research and scoping interviews, extensive desk research, consultations (both targeted and public consultations), direct interactions with stakeholders (via interviews and a validation stakeholder workshop) and case studies. Specific challenges and limitations were present at different stages of the study. The most significant ones for the consultation phase were the following:

- lack of statistical representativeness making the analysis mostly descriptive;
- sample size limitations for some groups;
- challenges in collecting cost data for different categories of stakeholder.

These limitations particularly concern data on the implementation of the Regulation. On multiple occasions in the past (independent review, impact assessment, reporting), stakeholders were reluctant or unable to present data in sufficient detail. While repeated efforts have been made to collect such data through dedicated outreach, the Commission has neither the legislative nor investigating authority to enforce data collection from private stakeholders, hence the persistent problem of data scarcity.

Specifics of the data collection process and limitations concerning costs and benefits are explained in more detail in the relevant chapter.

The assessment of the Regulation was measured against a notion of "success" understood as harmonised standards, European standards and standardisation deliverables being delivered in an effective, inclusive and timely manner in line with the needs of EU businesses and EU policies, and consequently the possibility for businesses to rely on the presumption of conformity stemming from compliance with harmonised standards (thus mitigating the costs linked to third party conformity assessment). A detailed description of the methodology, including the definition of success and related assumptions, the limitations, and the main sources of information for this evaluation are provided in Annex II.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

2.1. Description of the intervention and its objectives

2.1.1. How does the intervention fit in the wider policy framework?

Under the New Legislative Framework (NLF), the European Union provides for a body of EU legislation[8] that relies on technical standards to support implementation. This includes legislation regulating the internal market for goods and services. In addition to sector-specific legislation adopted since 2013, more recently, the European Union adopted important legislation that will inform and regulate the digital[9], green[10] and resilient transformation of EU industries. Much of this legislation provides for the delivery of technical standards and, thus, relies on the functioning and effectiveness of the Regulation.

[8] See legal instruments listed here: New legislative framework - European Commission, https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en
[9] Cf. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age_en
[10] Cf. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

Standards are, in principle, private and voluntary documents[11], which are stakeholder-driven and based on consensus. They are technical specifications that establish requirements for products, production processes, services or test methods and aim to ensure interoperability, compatibility, safety and quality, as well as environmental and consumer protection (where applicable). They can have an important impact on promoting innovation and competitiveness.

Through the Regulation, the European Union has established a legal framework to allow the development of harmonised European standards (hENs) in support of specific Union harmonisation legislation. This framework provides an *ex ante* format for the development of harmonised standards by the European standardisation organisations (ESOs: CEN, CENELEC and ETSI). In certain cases, requests to the ESOs may also target the development of other standards and standardisation deliverables in support of EU policies and legislation. Any standardisation request issued according to the provision of the Regulation is undertaken in an inclusive manner involving industry, societal stakeholders, research and public authorities.

The EU's approach to standardisation differs from methods employed elsewhere globally. In other regions, legislation often explicitly mandate adherence to certain standards, without the practice of foreseeing their incorporation *ex ante*, as is done in the EU. Additionally, certain regions often adopt a more authoritative, top-down approach to the development of standards, where government entities determine the standards with less input from other stakeholders (see Annex X).

One of the primary roles of harmonised standards is to facilitate trade of products in compliance with EU legislation within the Single Market. As such, European standards have had a harmonising effect across the Single Market. In 2010, the European Parliament had already recognised the significance of harmonised standards for the Single Market and recommended the expansion of their use in various EU policy areas beyond the Single Market.[12] Currently, harmonised standards support wider EU goals beyond the Single Market and are essential to the EU[13].

Once they are adopted and referenced in the Official Journal of the EU (OJEU), they aim at creating a harmonising effect across the Single Market and products that comply with harmonised standards, or parts thereof, are presumed to be compliant with specific essential requirements of Union harmonisation legislation, or parts thereof. Companies can rely on one or more harmonised standards to design and manufacture goods and services within the EU, rather than adhering to numerous national standards. In addition, through the presumption of conformity with essential requirements in EU legislation offered by harmonised standards, companies can avoid third-party

[11] European Commission, Impact Assessment, Accompanying document to the Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC, 2011, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2011:0671:FIN:EN:PDF.
European Commission, A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020, 2011, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52011DC0311.
European Commission, An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market, 2022, https://ec.europa.eu/docsroom/documents/48598.

[12] European Commission, A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020, 2011, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52011DC0311.

[13] Bjerkem, J., & Harbour, M., Europe as a global standard-setter: the strategic importance of European standardisation, Europe's Political Economy Programme, 2020.

conformity assessments, typically more costly. These cost savings contribute to the competitiveness of businesses.

From a broader perspective, standards, being technology neutral and performance-based, may facilitate the innovation of businesses. Innovators, academia and the research community could transfer their research and development knowledge to businesses through their participation in the drafting of standards[14].

In 2016, the European Commission recognised the importance of ICT standards as building blocks for the Digital Single Market and set out a comprehensive strategic and political approach to ICT standardisation[15].

In 2022, the European Commission further expanded the policy objectives of standards to address emerging global priorities[16]. Nations can leverage standards to advance their interests globally, and many non-EU countries are assertively using standardisation to give their industries a competitive advantage in market access, technology deployment and to generate dependencies in key industries[17]. Standards ensure product interoperability and quality, consumer and worker safety, and environmental protection. Thus, the EU's goals for a resilient, green, and digital economy could be compromised in case of other regions dominating standardisation at the international level. European standards do not define fundamental rights and values, but they play a critical role in safeguarding these rights and any mandate issued by the European Commission must be in alignment with the democratic principles and values of the European Union. Therefore, standards can be a policy tool at the international level to mitigate dependencies and promote EU values and EU objectives[18].

2.1.2. How does the intervention fit in the broader European standardisation system?

As described in Section 1 above, the Regulation governs the interface between the EU policy and regulatory activity and the private European standardisation system.

Organisational and business models of standardisation organisations are diverse and selected by each organisation independently. The European Committee for Standardisation (CEN) was founded in 1961 as a not-for-profit private organisation by the national standardisation bodies of the European Economic Community and EFTA, aiming to develop European standards and standardisation deliverables for products and services. It brings together the national standards organisations (NSOs) of 34 European countries, some of which are private organisations, while other function as government agencies. The ones representing EU Member States and EEA countries have been formally recognised as National Standardisation Bodies (NSBs) by the European Commission. CEN's revenue model is based on the annual contributions from its members (the 34 NSOs), which in turn have the exclusive right to sell the European standards copyrighted by CEN. The NSOs use part of the proceeds of the sale of standards to pay the annual membership contributions to CEN and retain the remaining income. Typically, the sale of

[14] Ibid.
[15] Communication from the Commission to the European Parliament, the Council, The European and Social Committee and the Committee of Regions on ICT Standardisation Priorities for the Digital Single Market, COM(2016)176 final
[16] European Commission, An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market, 2022, https://ec.europa.eu/docsroom/documents/48598
[17] Bjerkem, J., & Harbour, M., Europe as a global standard-setter: the strategic importance of European standardisation, Europe's Political Economy Programme, 2020.
[18] Ibid.

European and international standards expands the market opportunity to sell standards much beyond a market purely based on national standards. The business models of the different NSOs vary significantly, some of them relying mostly on the sale of standards to finance their activities, while others have differentiated their business models to generate also alternative sources of income. Industry and stakeholders can become members of the NSOs and participate to the standardisation activities against a fee.

The European Electrotechnical Committee for Standardisation (CENELEC) was founded in 1973 and is specialised in developing European standards for the electrotechnical sector. It has the equivalent legal nature, membership structure and business model as CEN, although it can have different members.

CEN and CENELEC have signed agreements with their international counterparts, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), respectively[19], resulting in a high level of convergence between the European and international standards, as well as a significant number of CEN and CENELEC standards being based on international standards.

The European Telecommunications Standards Institute (ETSI), created in 1988 and a recognised European Standardisation Organisation since 1992, has a different business model than CEN or CENELEC. It is based on a "direct membership" where CEPT-based organisations[20] are "full members", and others are "associate". Most revenues come from the fees of approximately 900 members, either full or associate. This allows ETSI to make their copyrighted standards freely available (in the English version only) on their website.

In terms of funding, operating grants issued by the Commission in 2023 accounted for 9%, 13.5% and 1% of the total budget of CEN, CENELEC and ETSI, respectively. On top of this, ESOs and NSBs receive action grants to fund specific actions in support of EU policy objectives. More funding details can be found in the analysis of the implementation of the Regulation in Section 3.1.2 below.

Harmonised standards (requested by the Commission, subject to the Regulation and in support of EU law) are only a small sub-set of the output of the three ESOs. The three ESOs also work on European standards (i.e. applicable across the entire Single Market, overriding national standards) and on other standardisation deliverables and technical specifications[21] (primarily initiated by industry).

Table 1 below shows the production numbers of harmonised standards developed per ESO compared to its other output. For the full time period between 1 January 2013 and 31 December 2024, ETSI has produced 29799 standardisation deliverables, of which 758 were European standards, of which 200 (less than 1%) were harmonised standards[22]. For CEN and CENELEC, these numbers are 19244 deliverables (including updates, amendments and corrigenda), of which 17117 were European standards, of which 5316 (28%) were harmonised standards (or other

[19] Vienna agreement (agreement on technical cooperation between ISO and CEN), 1991; Frankfurt agreement (IEC-CENELEC agreement on common planning of new work and parallel voting, Edition 3), 2016.

[20] Organisations from the 46 member countries of the European Conference of Postal and Telecommunications Administrations (CEPT), i.e. EU Member States, EU Candidate Countries, EFTA members, Andorra, Azerbaijan, Liechtenstein, Monaco, Montenegro, San Marino, United Kingdom and Vatican City.

[21] As defined in Regulation (EU) No 1025/2012, Article 2

[22] ETSI website, https://www.etsi.org/

standards requested by the Commission)[23]. Altogether, for all three ESOs, harmonised standards account for 11% of all standardisation deliverables produced between 2013 and 2024 (5516 out of 49043).

Table 1: Number of standardisation deliverables, European standards and harmonised standards developed by the ESOs

		2019	2020	2021	2022	2023
CEN / CENELEC	All standardisation deliverables	1694	1633	1602	1605	1463
	Of which European standards (EN)[24]	1566	1443	1423	1325	1330
	Of which harmonised standards (hEN)	432 **(26%)**	354 **(22%)**	422 **(26%)**	309 **(19%)**	242 **(17%)**
ETSI	All standardisation deliverables	1878	2852	1817	3358	1809
	Of which European standards (EN)	59	58	60	39	23
	Of which harmonised standards (hEN)	25 **(1.4%)**	12 **(0.4%)**	22 **(1.2%)**	13 **(0.4%)**	4 **(0.2%)**

Apart from the number of produced harmonised standards, it is also possible to consider the number of standards that have been cited in the OJEU. Looking at the entire portfolio of standardisation deliverables, CEN and CENELEC have 26678 standardisation deliverables, of which 3035 (11%) are cited harmonised standards (this is a lower percentage as it excludes produced standards that were withdrawn, not offered to the Commission or not cited for other reasons).

While harmonised standards make up only a relatively small part of the work of the ESOs and Commission funding accounts for a small part of the total budget of the ESOs, the significant relevance of harmonised standards (due to their role in the EU acquis) incentivises the ESOs to work on their delivery. However, with the Regulation not allowing the Commission to address standardisation requests to any organisations except the three ESOs, it can be questioned whether ESOs are sufficiently incentivised to adapt their ways of working in order to ensure timely delivery of high-quality standards. Furthermore, the ESOs fully rely on the willingness and ability of stakeholders and their experts to contribute to the standard-development process. While stakeholders are generally keen to engage with the ESOs on the development of harmonised standards that will provide a legal presumption of conformity, their business interests may not always fully align with the objective of a speedy delivery of harmonised standards that fully meet legal requirements and EU policy needs.

2.1.3. Intervention logic

The intervention logic that describes how the Regulation was expected to work and produce results and impacts when it entered into force, examines the interplay between the original needs and problems, the general and specific objectives of the Regulation, the inputs required to achieve these objectives, the activities and implementation processes and the expected impacts.

[23] PROJEX database and 'CEN CENELEC in figures, 2024 Q4', https://www.cencenelec.eu/stats/CEN_CENELEC_in_figures_quarter.htm
[24] Including amendments and corrigenda

While the use of standards and European standardisation as policy tools has been viewed as a success story[25], the 2011 Impact Assessment[26] identified three major problems at the origin of the Regulation, namely:

- The process for adopting European standards requested by the Commission was considered not fast enough.
- Underrepresentation of SMEs and societal stakeholders in the European standardisation process. SMEs could not spread the fixed costs associated with the participation in the European standardisation committees over a large enough volume of sales, and hence were rarely active in standard-setting. Despite the growing importance of standards in shaping society, consumers, environmental organisations, and workers' representatives seldom participated in standard-setting for reasons of costs, but also due to lack of awareness of the stakes.
- "Fora and Consortia Standards" could not be referenced in public procurement of ICT, notably the *non-formal* standards defined by non-formally recognised SDOs, fora and consortia, such as the IETF, W3C, MPEG, IEEE and OASIS, which are of particular relevance and importance in the field of ICT. This constrained the ability of public authorities in the EU to set up the necessary ICT infrastructure and created major interoperability problems within and between EU Member States.

At its origin, the Regulation had the following **general policy objectives**:

- increasing the contribution of standards and European standardisation to a better functioning of the internal market by supporting EU policy and legislation,
- stimulating growth and innovation, and
- fostering the competitiveness of EU enterprises, especially SMEs.[27]

Based on the overall policy objectives, four **specific objectives** were identified as follows:

- reducing the time taken by the standardisation process for standards developed at the request of the Commission;
- ensuring that SMEs and societal stakeholders are adequately represented in the standardisation process, especially for standards developed at the request of the Commission;
- broadening the use of ICT standards and thus enhancing interoperability through a more integrated European public procurement market for ICT products and services;
- removing ambiguities in the existing legal framework.

These specific objectives are linked to the broader general objectives through the role harmonised standards play in shaping markets[28]. Standards can help ensure quality and performance, improve measurement, codify knowledge, enhance compatibility and create economies of scale. Trusted

[25] European Commission, Impact Assessment, accompanying document to the Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC, 2011, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2011:0671:FIN:EN:PDF

[26] Ibid.

[27] Ibid.

[28] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, 2021b, https://ec.europa.eu/docsroom/documents/50114

standards also lower risk and foster confidence, key aspects of well-functioning markets. Standards also help prevent market failures by promoting safety, reducing uncertainty, and aligning market behaviour with societal goals. Overall, these intermediate effects can contribute to broader economic outcomes in terms of competitiveness, productivity and innovation (see Section 4.1.1.5 below).

To achieve the above-mentioned objectives, the Regulation sets rules for:

- The cooperation between the ESOs, NSBs, Member States and the Commission.
- The development process of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies.
- The identification of ICT technical specifications eligible for referencing in public procurement.
- The financing of European standardisation.
- The stakeholder participation in European standardisation.

The Regulation then defines activities, which are geared towards achieving the above objectives (also referred to as **inputs)**. These activities are described in more detail in Annex VIII.

- Activities to enhance transparency (Articles 3 to 4)
- Activities to enhance stakeholder participation and inclusion (Articles 5 to 7)
- Activities to support Union legislation and policies (Articles 8 to 12), including the detailed procedure of how the European Commission requests standards to the European standardisation organisations (Article 10)
- Activities to support identification of ICT technical specifications (Articles 13 and 14)
- Activities to finance European standardisation (Articles 15 to 18). The EU budget finances the ESOs and the so-called 'Annex III organisations', stakeholder organisations meeting the criteria listed in Annex III of the Regulation, through grants. Reporting requirements are included in Article 24.

In the short term, expected **outputs** from the application of the Regulation are:

- Standardisation requests by the Commission;
- Annual Union Work Programme on European standardisation;
- ESOs and NSBs/NCs/NSOs work programmes;
- Draft standards and deliverables shared by the ESO;
- NSBs/NCs/NSOs annual reports to the ESOs;
- ESOs annual reports to the Commission;
- List of ICT technical specifications to be eligible for referencing in public procurement;
- EU financing to ESOs and Annex III organisations;
- Formal objections.

In the medium term, expected **outcomes** from the application of the Regulation are:

- increased speed of European standard-setting process;
- increased stakeholders' involvement in standardisation processes;
- increased interoperability of ICT networks and systems;
- removed overlaps among standards at national and European level.

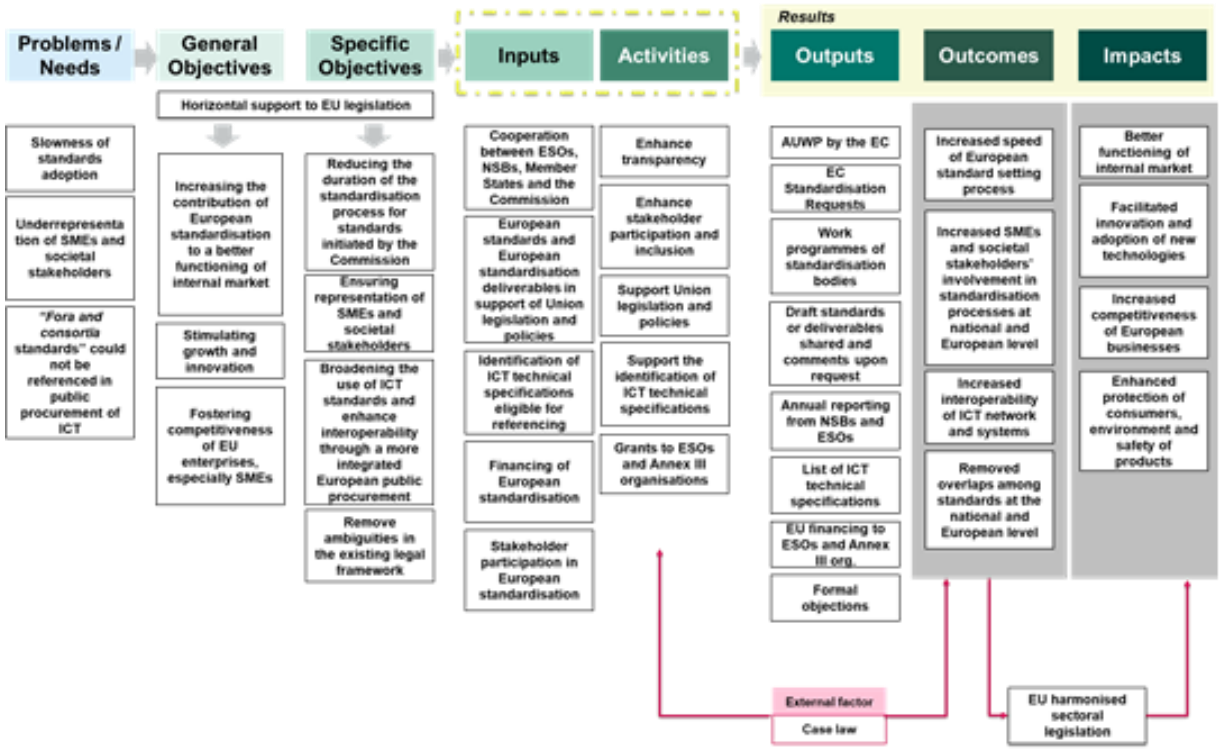
Finally, long-term **impacts** expected by the application of the Regulation are:

- better functioning of the internal market;
- facilitated innovation and adoption of new technologies;
- increased competitiveness of European businesses, especially SMEs;
- enhanced protection of consumers, of workers, of the environment.

The causal chains resulting in these impacts rely on the horizontal nature of the Regulation in supporting other EU legislative acts (in particular the NLF). The implementation of the EU harmonised sectoral legislation bridges the outcomes of the Regulation with its impacts, i.e. if the outcomes of the Regulation are achieved, it was expected that the sectoral legislation is successful and thus it was expected that long-term impacts will be achieved. This interplay between the Standardisation Regulation, the NLF and EU harmonised sectoral legislation should be considered in the evaluation of the impacts in this report.

By assessing the above outputs, outcomes and impacts, the evaluation acknowledges external developments like geo-economic developments as well as applicable jurisprudence from the ECJ, which has significantly influenced the application of the Regulation.

Figure 1: Intervention logic



2.2. Point(s) of comparison

This section of the evaluation looks at the baseline scenario (or points of comparison) as to how the problems would have evolved without the intervention of the Regulation as set out in the

Impact Assessment of 2011[29], while taking into account the two monitoring exercises[30] that have been conducted in 2015[31] and 2020[32] (European Commission, 2022).

2.2.1 The problems and their expected evolution

On the three problem areas identified in the impact assessment, the following evolution was expected without the intervention of the Regulation:

- **Speed**: a reduction in the duration of standard-setting processes was already observed in the years immediately before the Regulation was adopted. This trend was expected to continue, but also to soon reach its limit. This was reportedly due to the need to heed the fundamental principle of consensus-building. The impact assessment report referred that the overall time to develop one harmonised standard varied widely among each hEN, reaching in some cases as much as 10 or 15 years[33].
- **Stakeholder participation/inclusiveness**: low level of representation of societal interests and viewpoints in the standards-development process, especially at national level with little or no evolution of the problem expected; and
- **Lack of uptake of ICT standards** with an impact on inter-operability objectives of the European Union with little or no evolution of the problem expected.

2.2.2 Monitoring exercises on the implementation of the Regulation

During the period of application of the Regulation, several monitoring exercises were conducted. They delivered certain limited insight into the development of the three problems.

The first monitoring exercise in 2013[25] identified an improvement of the standardisation speed. On stakeholder participation and inclusiveness, it only provided qualitative conclusions. No specific conclusion was provided on the third problem, i.e. referencing of ICT technical specifications.

Subsequently, a more recent monitoring exercise on the implementation of Article 24 – of 2015 (European Commission, 2022) and of 2020 (European Commission and EY, 2021)[34] – concluded improvements in speed in some specific phases, an increase in the acceptance of standardisation requests by ESOs, as well as the level of acceptance of the drafted hENs by the Commission, which were based on some quantitative data.

On inclusiveness, these exercises again provided qualitative conclusions. On the identification of "Fora and Consortia standards", the monitoring exercises observed that the European Multi-Stakeholder Platform on ICT Standardisation[27] advised the Commission on ICT technical

[29] *Cf.* Section 3.1 of the Impact Assessment Accompanying document to the Proposal for a Regulation of The European Parliament and of The Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC (COM(2011) 315 final)

[30] Please note that the two exercises had two different scopes and objectives and were not meant to conduct the same monitoring; therefore the comparison among the two is limited.

[31] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Independent review of the European standardisation system – Final report, 2015, https://data.europa.eu/doi/10.2873/720891

[32] Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2015 to 2020, COM(2022) 30

[33] *Cf.* Impact Assessment, p. 9

[34] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Independent review of the European standardisation system – Final report, 2015, https://data.europa.eu/doi/10.2873/720891

specifications, resulting into 8 identification decisions covering 83 technical specifications by the Commission[35] (see Section 3.1.3 below).

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

Since the adoption of the Regulation in 2012, both the implementation of the Regulation and the situation on the ground have developed. Developments related to both aspects are presented in this section. As background information, a short overview of the Regulation and the development process of a harmonised standard is provided in Annex VIII.

3.1. Implementation of the Regulation

3.1.1. Standardisation process: duration and prioritisation

As of October 2024, there are 3,624 deliverables (main standards, amendments, corrigenda, superseded documents) cited in the OJEU, corresponding to 2,961 consolidated and unique harmonised standards[36]. The average harmonised standard cited in the OJEU was adopted by European Standardisation Organisations 12 years ago (see Table 2 below)[37]. Some standards, particularly under the Low Voltage Directive 2014/35/EU, were adopted over 30 years ago.

Table 2: Average age[38] of cited standards in the OJEU

Age (Years)	Number of cited standards	Share
5 or less	519	18%
5-10	677	23%
10-15	760	26%
15-20	685	23%
20-25	265	9%
25-30	40	1%
30-35	13	<1%
35-40	1	<1%
40 or more	1	<1%
	2,961	100%

Source: European Commission's internal database in October 2024

According to the evaluation study, the Regulation has enhanced the speed of the European standards development process to a moderate extent, with an average of 6 years to deliver a harmonised standard in comparison to 10 years before the Regulation. However, the process can be much longer for certain standards, both before and after the Regulation[39] (see assessment in Section 4.1.1 below).

The entire process for harmonised standards comprises three phases: (A) the adoption of the standardisation request by the Commission and its notification to the ESOs, (B) the technical development and delivery of the standard or standardisation deliverable by the ESOs, and (C) the submission of the standard to the Commission, the assessment of the compliance of the

[35] For more details see ICT technical specifications, https://single-market-economy.ec.europa.eu/single-market/european-standards/ict-standardisation/ict-technical-specifications_en
[36] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.4
[37] When a standard is amended, only the date of the latest amendment has been taken into account for these statistics.
[38] Measured by the time between publication by the relevant ESO and October 2024
[39] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.4

standard and the publication of its reference in the Official Journal of the EU. This process is described in more detail in Annex VIII.

From 2014 to 2024, the average time taken for the first phase (Phase A) has slightly increased from 1.5 (2014) to 1.8 years (2024), with a peak in 2018 at three years[40]. The implementation of standardisation requests in 2018 and 2019 was influenced by ESOs' rejections of four requests following the Case C-613/14 (also known as the "James Elliot case"[41], see background information in Annex IX) and prolonged debates about new mandates for personal protective equipment and medical devices. The overall time of 1.8 years covers consultations with ESOs, Member States, Annex III organisations and other stakeholders, the vote in the Committee on Standards and Commission-internal processes.

The second phase (Phase B), the procedure for delivering a requested European standard or standardisation deliverable by the ESOs, has marginally increased in duration between the 2009-2012 and the 2013-2024 period. The average time is for 2013-2024 is 3.0 years for CENELEC and 3.2 years for CEN and ETSI, yet it fluctuates significantly[42]. A decreasing trend was visible immediately after the adoption of the Regulation (between 2012 and 2016), followed by an increase with a plateau between 2.5 and 3.5 years. The phase usually comprises a lengthy consensus-building process.

As part of the third phase (Phase C), the duration of the delivery of the standard by the ESOs to the Commission has decreased and then stabilised in recent years, fluctuating between three and four months after adoption by the ESOs. The time for the subsequent steps towards publication in the Official Journal (OJEU) varies with a peak of 1.4 years in 2023 before decreasing to 1.1 year in 2024[43]. This includes the conclusion of the compliance assessment by the Commission services to assess whether the documents meet the standardisation requests (as foreseen by Article 10(6) of the Regulation). In this process, the Commission services are sometimes supported by the Harmonised Standards consultants ("HAS consultants"), who are however more structurally involved during the drafting phase by the ESOs.

Significant delays in the process can occur across the three phases. The evaluation study identified three different challenges: (1) prolonged negotiations, revisions, and requests for extensions of standardisation requests, (2) consensus building, resource limitations and technical knowledge gaps, and (3) quality control issues in compliance assessments[44].

With regard to delays in the consensus-building process, case studies revealed challenges in reconciling a potential stakeholder interest in cost-effective measures to fulfil legislative requirements with the policy makers' interests in covering all potential risks. This can create delays as industry may not be incentivised to participate in the development of a standard that could carry more costs than benefits for their businesses. Another challenge is that the ESOs selected under the Regulation may not always be able to involve the relevant industry experts for

[40] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.4
[41] Case C-613/14: Judgment of the Court (Third Chamber) of 27 October 2016, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62014CA0613
[42] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.4
[43] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Figures 3.9 and 3.10
[44] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.4.3

technical standards. In addition, a lack of expertise for some products can be a reason for delays (as seen in the case of standards for pyrotechnics). In other cases, procedural discussions, in particular when there are international standards related to the harmonised standards under development, may delay the process.

With regard to quality issues, data from 2016 to 2024 shows that the Commission has found lack of compliance for a significant number of standards. Out of 525 standards rejected, 202 were rejected for non-eligibility (for instance when the legislation corresponding to the standardisation request had been repealed by the time standards were submitted to the Commission, or when standards do not align with the specific legislation under which they have been proposed) and 323 were rejected for non-compliance with the requirements.

Significant quality issues were also identified in the assessments of draft harmonised standards carried out by dedicated consultants (technical experts in the relevant fields). From July 2015 to March 2018 the system of New Approach Consultants (managed by the CEN-CENELEC Management Centre but financed via a grant given by the Commission[45]) assessed 3071 draft harmonised standards: in 1644 cases (54%) the standards received a negative assessment, meaning that the documents were not considered as adequate to ensure compliance with the relevant legislation. The picture differed however greatly between sectors: for instance, 156 out of the 208 (75%) draft standards assessed for medical devices received a negative assessment[46].

In April 2018 the New Approach Consultants were replaced by the system of HAS Consultants, managed by the Commission with the administrative support of an external contractor. The new system covered more sectors (21 in total) and included also ETSI standards under its scope of work. The HAS consultants carry out their work under instructions and training provided by the Commission services. The first HAS consultants contract ran from April 2018 to March 2022. During that period, 2793 draft harmonised standards were assessed, with 1919 standards receiving a negative assessment (69%[47]). An analysis of the findings of the 1150 assessments carried out between July 2020 and December 2021 revealed both shortcomings on formal elements, but also in many cases on substantial elements (such as problems with the technical content, with the risk assessment or with the technological neutrality principle).

Through an analysis of case studies, the evaluation study also assessed specific cases where the Commission's compliance assessments, supported by HAS consultants, uncover quality issues that prevent standards from meeting publication requirements, leading to rejections or the need for further revisions. In certain cases, this has led to major delays, for instance for standards on equestrian helmets where the process to revise the standard took more than 10 years[48].

Important measures for more upfront consultation and interaction between policymakers, innovators and standardisers were established in 2023 as part of the ESOs-European Commission-EFTA Taskforce on "Timely European Standards for a Green and Digital, Single and Global Market". As a result, Commission services have started interacting with the European

[45] The system of New Approach Consultants covered 16 NLF sectors, and only assessed draft harmonised standards developed by CEN and CENELEC. ETSI standards were not under the scope of this system.
[46] Based on the Commission's analysis of the final reports of the grant recipients.
[47] Based on the Commission's analysis of the results of the HAS consultants' assessments.
[48] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Annex VII

standardisation organisations at an early stage - sometimes already during the drafting process of prospective legislation. A more structured approach was established through the High-Level Forum on European standardisation, in which -for instance- the Standardisation Request in support of the Data Act was instructed in a multi-stakeholder format.

Article 11 of the Regulation introduced a process for formal objections, allowing Member States or the European Parliament to object if a harmonised standard fails to fully meet the requirements of relevant Union legislation. Between 2014 and April 2024, 41 formal objections were filed. 68% of formal objections resulted in no outcome, while 22% led to restrictions (hence a limitation of the scope of applicability of the standard) and 10% resulted in standards being maintained. The most common reasons for formal objections are safety and health concerns (27% of the objections raised), non-compliance with directives and regulations (22%) and environmental and quality concerns (17%)[49].

The qualitative assessment of cases of formal objections revealed challenges particularly around efficiency, procedural demands and timely responsiveness to safety concerns. For instance, formal objections against the standard for household appliances under the Low Voltage Directive (LVD) triggered a process that spanned several years and numerous revisions, culminating in a withdrawal of the outdated standard from the Official Journal. This shows that -despite the possibility to raise formal objections- extensive and slow revisions can result in potentially unsafe standards remaining in place until final decisions are enacted.

Over the last years, in many sectoral legislative tools, the co-legislators started to pre-empt situations, in which harmonised standards are not available, or not in conformity with EU law. Many EU Regulations now dispose of legal provisions that allow the Commission to adopt implementing acts that provide for common specifications as a fallback to the non-delivery of harmonised standards[50]. These legal provisions are to be invoked in exceptional cases but respond to the experience during the implementation period of the Regulation (see Section 4.1.3.2). On 21 May 2025, as part of its fourth simplification omnibus package, the Commission proposed to apply these provisions across a wider range of product legislation in a coherent manner.

Article 8 of the Regulation introduced the requirement for the Commission to adopt an Annual Union Work Programme for European standardisation (AUWP). Since 2023, the Commission has enhanced its stakeholder consultation on the work programme through the newly established High-Level Forum on European Standardisation (HLF), which includes national representatives, industry, civil society and academia. The AUWP is complemented by the ICT Standardisation Rolling Plan, which identifies ICT standardisation needs in support of EU policies.

The AUWP has been increasingly used for prioritisation purposes, culminating in key priorities identified in the 2022 and 2023 AUWPs, aligned with strategic objectives of the Union and supported by action grants. However, despite the prioritisation in the AUWP and the allocation

[49] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.5.1

[50] 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), Directive (EU) 2016/1629 (on technical requirements for inland waterway vessels), Directive (EU) 2016/2102 (Web Accessibility Directive), Regulation (EU) 2023/1230 (Machinery Regulation), Regulation (EU) 2023/1542 (on batteries and waste batteries), Regulation (EU) 2024/1689 (AI Act), Construction Products Regulation.

of these grants, many initiatives remained without response from the ESOs. In 2022, only one out of eight priority areas elicited a response, leaving crucial sectors like COVID-19 vaccine production, 'smart contracts' and hydrogen technology without the initiation of standards-development activities. In 2023, responses were received for only three out of nine policy priority areas for standards.

3.1.2. Stakeholder representation, inclusiveness, transparency and funding

Article 5 of the Regulation introduced a requirement for 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"*. European stakeholder organisations, foremost the ones listed in Annex III of the Regulation, have been given an important role.

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[51]. 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[52]. 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[53]. However, interviews with Annex III organisations reveal that participation is not always perceived as leading to real effects[54].

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/NCs/NSOs in which societal interests are represented) varies between 47% and 77%, in 2022[55]. Interviews with Annex III organisations, public authorities and national societal organisations suggest that national societal organisations are not adequately represented in NSBs[56].

Representation and direct participation by SMEs in both national and European technical committees is recognised as crucial (Recital 20 of the Regulation). Article 6 of the Regulation requires national standardisation bodies to encourage access of SMEs to standards development. In reality, their involvement varies, with 31 out of 34 in CEN-CENELEC's NSBs/NCs 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/NCs/NSOs liaise with stakeholder groups to recruit SME representatives for technical committees and working

[51] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.8
[52] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.9
[53] Standards and Society, The ETSI 3SI Programme, https://www.etsi.org/images/files/Brochures/ETSI-3SI-Brochure-WEB.pdf
[54] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.9
[55] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.2.3
[56] See Annex V, Synopsis report, Section 'Interviews'

groups. 22% of ETSI's membership is made up of SMEs[57] (while 99% of all businesses in the EU are SMEs[58]). 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[59].

CEN, CENELEC and ETSI have various workstreams to foster cooperation with universities and researchers[60].

Transparency is an important pre-requisite to ensure fair stakeholder representation and is among the key globally recognised principles of standardisation[61]. This involves transparency of the planned work of the ESOs and NSBs (as required by Article 3 of the Regulation), transparency of the standards that are under development (as required by Article 4 of the Regulation), but also -more broadly- transparent and fair access to European standards for all market players and consumers throughout the Union (as stipulated in Recital 43 of the Regulation).

As regards transparency of planned work, the three ESOs and most NSBs publish their work programmes online. Work programmes for 2 NSBs were not found online at the time of the evaluation study[62]. In the targeted consultation, industry views about the accessibility of ESO and NSB work programmes were mixed[63].

As regards transparency of standards, the legal requirement in Article 4 relates specifically to transparency between the ESOs and the NSBs/NCs/NSOs, and between these and the Commission. Article 4 requires ESOs and NSBs to provide draft national and European standards to other ESOs or NSBs or to the Commission upon request, and to reply to their comments. The implementation has evolved over the past years. Between 2015 and 2019, NSBs failed to fulfil all requests for draft standards to be shared[64]. However, between 2020 and 2022, both ESOs and NSBs fulfilled all requests[65]. Furthermore, CEN, CENELEC and ETSI have established a range of cooperation activities with NSBs and NSOs[66]. NSBs have also implemented the requirement to allow all relevant parties to submit comments, although not all have established online platforms for the submission of comments (85% of NSBs, 74% of NCs, 66% of NSOs).

Beyond transparency of standards among the standardisation organisations and the Commission, Article 6 of the Regulation introduced a requirement for national standardisation bodies to encourage and facilitate the access of SMEs to standards and standards development. Free access or special rates to participate in standardisation activities and free access to draft standards are listed in Article 6 as two of the possible ways to achieve this goal. Some NSBs/NCs/NSOs

[57] ETSI Article 24 Report (2022)
[58] Communication from the Commission, SME Relief Package, 12 September 2023, COM(2023) 535 final
[59] See Annex V, Synopsis report, Section'Interviews'
[60] See further details in Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.9.2.
[61] Principles for the Development of International Standards, Guides and Recommendations, agreed upon by the Technical Barriers to Trade Committee (TBT) in 2000
[62] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.1
[63] On the general accessibility of ESO work programmes, 28% strongly agrees, 20% agrees, 12% disagrees, 16% neither agrees nor disagrees, 24% doesn't know. On the general accessibility of NSB/NC work programmes, 16% strongly agrees, 24% agrees, 8% disagrees, 20% neither agrees nor disagrees, 28% doesn't know. See Synopsis report in Annex V.
[64] European Commission and EY, Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24) – Final report, Publications Office, Luxembourg, 2021, p. 7, https://data.europa.eu/doi/10.2873/504681
[65] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.2
[66] Idem, Table 3-2

provide free access to standards, while others offer reduced participation fees, but only 54% of NSBs provide free access to draft standards under development.

Recent ECJ jurisprudence, namely judgement C-588/21 P[67], emphasised the role of harmonised standards as part of EU law, and affirmed the application of Rule of Law principles in line with Art. 2 of the EU Treaty on transparency and accessibility. The Court specifically ruled that an overriding public interest applied within the meaning of the last clause of Article 4(2) of Regulation (EC) No 1049/2001 on access to documents. While the ECJ did not specifically draw on the transparency provisions of Regulation (EU) 1025/2012, it ruled that harmonised standards had to be made accessible to natural or legal persons upon their request.

The three European Standardisation Organisations listed in Annex I (CEN, CENELEC and ETSI) and the Annex III organisations are financed by the Commission through Framework Partnership Agreements (FPAs). This entails both action grants and operating grants[68].

On average, the Commission funds around EUR 9.45 million of action grants per year to the ESOs, which represents 43% of the Commission's yearly budget for standardisation[69]. Funding through action grants varies over time but has shown a gradual upward trend. In terms of operating grants, CEN received EUR 2.016 million on average, CENELEC EUR 631 000 and ETSI EUR 1.739 million. In 2023, the Commission's operating grants accounted for only 9%, 13.5% and 1% of the total budget of CEN, CENELEC and ETSI, respectively (see Annex VI). Other revenues for CEN, CENELEC and ETSI depend on their business models, as described in Section 2.1.2 above.

EU funding to Annex III organisations has grown from 2015 to 2023 (see Figure 2 below). ANEC, ECOS and ETUC annually received on average operating grants amounting to EUR 1.37 million, EUR 833 000 and EUR 366 000, respectively[70]. SBS received EUR 1.65 million in action grants.

The Annex III organisations have reported increased participation in technical work in their reports submitted under Article 24 of the Regulation while they reported significant challenges in contributing to ISO and IEC technical committees[71]. The establishment of ISO / IEC liaisons in technical committees requires around nine months, hampering the effective contribution to the technical work[72].

Figure 2: EU financing to Annex III organisations from 2015 to 2023

[67] Judgment of the Court (Grand Chamber) of 5 March 2024, Public.Resource.Org, Inc. and Right to Know CLG v European Commission, Case C-588/21 P, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62021CJ0588

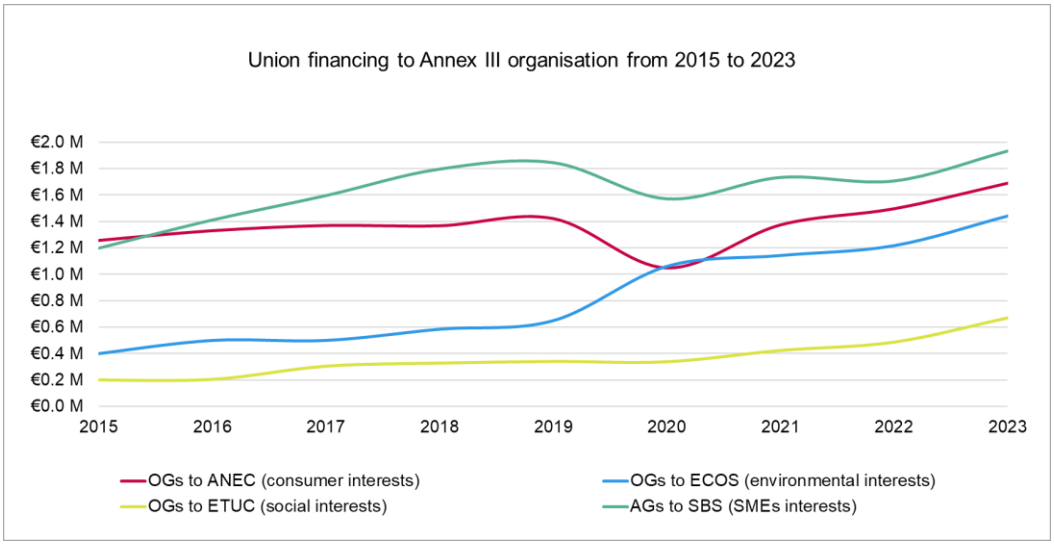
[68] Action grants fund a specific action intended to help achieve the EU policy objectives; operation grants fund the operating costs of an ESOs and Annex III organisations as defined by Articles 15(1) and 16 of the Regulation, including technical work, studies, expert training and the promotion of European standards at the international level.

[69] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.7

[70] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.8

[71] Reported in the 2022 Article 24 Report from SBS, as well as the targeted consultations. See Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.1, Box 11

[72] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 3.1.8, EQ2, Box 12



Source: European Commission Union financing data.

3.1.3. ICT specifications

Articles 13 and 14 of the Regulation allow the identification of common ICT technical specifications for referencing in public procurement. From 2014 to 2017, 83 ICT technical specifications have been officially identified. No specifications were published afterwards[73].

The Interoperable Europe Act[74] adopted in 2024 foresees in its Article 8 to provide access to ICT technical references eligible for referencing in accordance with Article 13 of the Regulation.

In recent years, an increasing range of digital legislation that uses harmonised standards for compliance purposes has been adopted (such as the AI Act, the Cyber Resilience Act and the Data Act, see Section 3.2.1 below).

3.2. Evolving standardisation needs

3.2.1. Legislative needs

The EU acquis referring to Regulation (EU) 1025/2012 has expanded significantly since its adoption. Key policy initiatives in support of EU flagships, notably the EU Green Deal, Digital Decade and Industrial Strategy, rely heavily on standardisation (see Box below).

Box: Legislation and policy referring to or relying on Regulation (EU) 1025/2012

A. Referring to the Regulation 1025/2012: AI Act, Batteries, Machinery, Hydrogen, Data Act, Ecodesign for Sustainable Products, Cyber Resilience Act, General Product Safety, Energy Labelling, Cosmetic products, REACH Regulation, General product safety, Interoperability of the rail system, Inspection of pesticide application equipment, Safety of Toys, Restriction of use of certain hazardous substances (RoHS), Pyrotechnic articles, Recreational craft (RCD), Explosives for civil uses, Simple Pressure Vessels (SPWD), Electromagnetic Compatibility (EMC), Non-automatic weighing instruments (NAWI),

[73] At the end of 2024, the Multi-Stakeholder Platform decided to resume the identification process of ICT technical specifications to be referenced in implementing acts related to the European Digital Identity (eIDAS) Regulation. However, this falls outside the temporal scope of this evaluation.

[74] Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act)

Measuring instruments (MID), Lifts, Equipment explosive atmospheres (ATEX), Low Voltage (LVD), Radio Equipment (RED), Pressure equipment (PED), Accessibility of the websites and mobile applications of public sector bodies (WAD), Cableway installations (CWR), Personal protective equipment (PPER), Appliances burning gaseous fuels (GAR), Medical Devices, In Vitro Diagnostic Medical Devices, Plastic caps and lids, Unmanned aircraft systems, Construction Products (CPR), Community eco-management and audit scheme (EMAS), Active implantable medical devices, Packaging and packaging waste, Community postal services.

B. **Otherwise relying on standardisation:** European Green Deal, Circular Economy Action Plan, Clean Industrial Deal, Digital Decade, Measures for a high common level of Security across the Union (NIS2), Cyber Security Act (CSA), Digital Service Act (DSA), Framework for ensuring a sector and sustainable supply of raw materials European Digital Identity, Data Governance Act, Financial Data Access, Interoperable Europe Act, Intelligent Transport System (ITS), Web 4.0 and virtual worlds strategy, Multimodal Digital Mobility Services (MDMS), EU action Plan for Grids.

New legislation relying on Regulation (EU) No 1025/2012 includes not only physical products and services, but also digital technologies, software and related aspects such as cybersecurity and data protection. In addition, while initially essential requirements primarily related to safety and interoperability, other aspects, such as the protection of fundamental rights and EU values, have become increasingly relevant. This was emphasised in the 2022 EU Standardisation Strategy: *standards do not only have to deal with technical components, but also incorporate core EU democratic values and interests, as well as green and social principles*".[75] For instance, the artificial intelligence (AI) standards that are currently under development under the AI Act cannot be dissociated from fundamental rights and EU values.

3.2.2. Competitiveness needs

Since the adoption of the Regulation in 2012, standardisation has evolved from a Single Market tool into a driver and prerequisite for industrial competitiveness and technological sovereignty. The speed of standardisation has become increasingly important as industry relies on standards in fast-moving technology areas, notably in support of the green and digital transitions. The 2016 Communication on ICT standardisation priorities identified the importance of standards to support the competitiveness of EU businesses[76]. The 2024 report on the future of European competitiveness identifies the need for standardisation in key strategic areas, notably defence, telecoms, automotive, transport and clean technologies.[77] Similarly, the 2024 report on the future of the Single Market highlights the importance of standardisation in cybersecurity, circular economy, 5G/6G, cleantech and sustainable products.[78] In parallel, for European businesses and in particular SMEs to be competitive, there is an important and increasing need to reduce administrative burden and to simplify processes in the Single Market[79]. In addition, the 2025

[75] European Commission (2022) An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market, https://ec.europa.eu/docsroom/documents/48598
[76] COM/2016/0176 final
[77] Draghi M (2024) The future of European competitiveness – A competitiveness strategy for Europe
[78] Letta E (2024) Much more than a market – Speed, Security, Solidarity Empowering the Single Market to deliver a sustainable future and prosperity for all EU Citizens
[79] COM(2023) 168 final, Communication on long-term competitiveness of the EU: looking beyond 2030

Competitiveness Compass highlighted that the European standardisation system lacks responsiveness to faster innovation cycles in emerging technologies[80].

3.2.3. Geopolitical context

While the EU has traditionally had a strong footprint in international standardisation activities, other countries and regions have become increasingly strategic and assertive in international standardisation. For instance, China launched its 'China Standards 2035' project and has significantly strengthened its presence in international standardisation in recent years[81]. The United States published its 'National Standards Strategy' in 2023[82]. Data from the AFNOR international barometer on participation in global technical committees shows a relative decrease in the EU's role compared to the roles of China and Japan over the last ten years[83].

On top of this, third countries have started to use standards to promote strategic economic and geopolitical objectives. For example, China has incorporated the use of standards as a key component of its Belt and Road Initiative (BRI), while the United States has done the same within its America First Policy.[84] As part of the 2022 EU Standardisation Strategy, the Commission underlined the need to improve coordination between EU Member States, ESOs, national standardisation bodies and EU stakeholders to strengthen the EU's voice in global standardisation.

4. EVALUATION FINDINGS

4.1. To what extent was the intervention successful and why?

4.1.1. Effectiveness

4.1.1.1. Reducing the duration of the standards-setting process

As outlined in Section 2.1.3 above, based on the impact assessment of the Regulation[85], the first specific objective of the Regulation is *"reducing the time taken by the standardisation process for standards developed by the Commission"*. Success in this regard can be defined as high-quality harmonised standards that meet the needs of EU policies and legislation being delivered significantly faster than at the time of adoption of the Regulation.

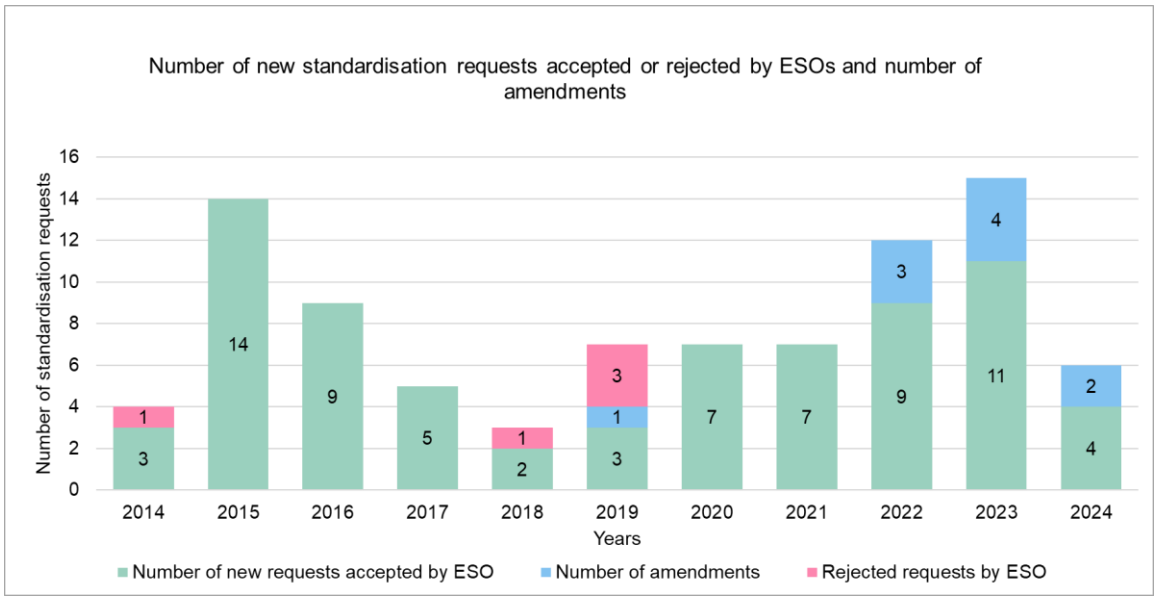
With this in mind, the evaluation will first assess whether harmonised standards are effectively delivered with sufficient quality. Subsequently, it will assess the speed of the process. When defining success in terms of speed, it is not possible to set a specific target duration, as this depends on the circumstances of each standardisation request (such as legal, policy, market, industry or technology needs). Therefore, this evaluation will first assess whether the duration

[80] COM(2025) 30 final, A Competitiveness Compass for the EU
[81] Seconded European Standardisation Expert for China (SESEC), https://sesec.eu/
[82] United States Government National Standards Strategy for Critical and Emerging Technology, May 2023, https://www.whitehouse.gov/wp-content/uploads/2023/05/US-Gov-National-Standards-Strategy-2023.pdf
[83] AFNOR (2024) Baromètre international, Édition 2024
[84] Bjerkem, J., & Harbour, M., Europe as a global standard-setter: the strategic importance of European standardisation, Europe's Political Economy Programme, 2020.
[85] European Commission, Impact Assessment, Accompanying document to the Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC, 2011, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2011:0671:FIN:EN:PDF

has been significantly reduced on average, and then whether this duration meets certain legal, policy and market needs. In this context, it will consider the effects of the prioritisation in the Annual Union Work Programme on European standardisation (one of the outputs of the Regulation). In addition, in light of the increased competition in global standard-setting, it will assess if the duration of the process is internationally competitive (compared with non-ESO standardisation processes). Finally, it will explore the root causes of an insufficient reduction of the duration of the process.

In terms of effectively delivered harmonised standards upon request by the Commission, between 2013 and 2024 CEN, CENELEC and ETSI have adopted around 4 940 standards and amendments or corrections to standards which have been delivered to the Commission by the end of 2024. Between 2014 and 2024, ESOs rejected only 5 standardisation requests from the Commission (each of which can contain multiple requested standards) (see Figure 3 below). The number of accepted standardisation requests has fluctuated, with a low number in 2018 and 2019 (2 and 3 requests, respectively), likely due to the impact of the James Elliot ruling, as this resulted in stricter requirements in the standardisation requests. However, there was a gradual recovery in subsequent years, reaching a high of 11 requests in 2023.

Figure 3: Number of standardisation requests accepted or rejected by ESOs



Source: Evaluation study, Figure 3-5, based on SIGNIFERI data

The quality of the delivered standards can be assessed by considering the number of formal objections by Member States to published harmonised standards, as well as the results of quality assessments prior to publication. In terms of formal objections, Member States have filed 41 formal objections between 2014 and 2024, 22% of which led to restrictions (hence a limitation of the scope of applicability of the standard, see Section 3.1.1). During the standardisation process, quality assessments are conducted by the Commission and HAS consultants, with 68.7% of standards receiving a negative assessment by HAS consultants between 2018 and 2022, either for formal or substantive reasons, as described in Section 3.1.1 above. In addition, data from the HAS assessments shows that a significant number of draft harmonised standards that are offered by the ESOs are ultimately not (yet) cited: between 2013 and 2024, only 3272 out of 4942 offered

standards have been cited. This suggests that standards under development regularly fail to meet legal requirements, which can cause significant delays in the process (see below).

In terms of speed of standard-development, according to the accompanying evaluation study, the time to develop a harmonised standard has decreased to a moderate extent, with an average of 6 years to deliver a harmonised standard in comparison to 10 years before the Regulation. However, the process can be much longer for certain standards, both before and after the Regulation[86].

The duration of the different phases of the standardisation process (as outlined in Section 3 above) before and after the Regulation are shown in the Table 4 below.

Table 4: Pre/post Regulation 1025/2012 comparison of average duration of standard development at the request of the Commission. *Source: Evaluation study, Section 4.1.1.1*

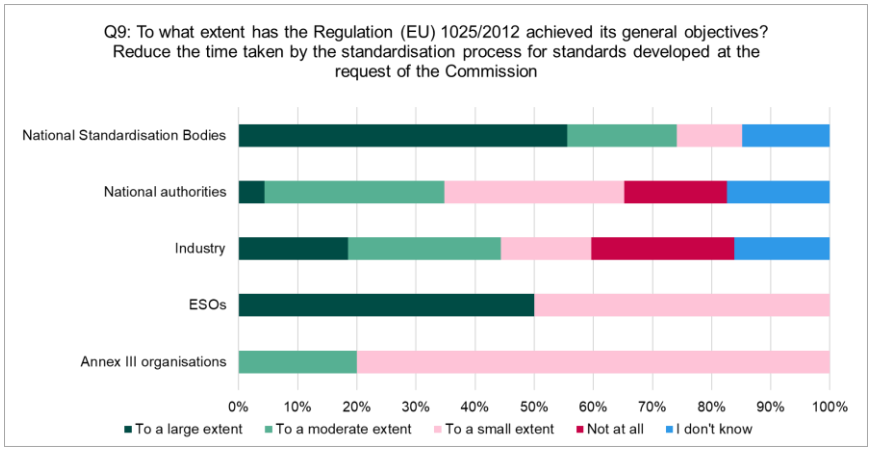
		Baseline (before the Regulation) determined in the evaluation study		After the Regulation (assessed in 2024)
Phase	**Subphase**	**Low estimate**	**High estimate**	
Phase A: adoption & notification of standardisation request	Standardisation requests adopted by the European Commission	0.8 year (9 months)	0.8 year (9 months)	**1.7 years**
Phase B: Delivery of the standard	Acceptance of standard request by the ESOs	0.7 years (5 months)	0.7 years (5 months)	**0.1 year (1 month)**
	Drafting stage	2.7 years	5 years	**3.1 years**
Phase C: Submission and publication	ESO submission to the European Commission	5.4 years	5.4 years	**0.3 years (3 months)**
	Citation time in the OJEU	Not available	Not available	**0.9 years (11 months)**
Total		9.6 years	11.9 years	**6.1 years**

This shows that some phases of the process have increased in time, while others have decreased. Notably, the time needed for ESOs to submit the standard to the Commission has significantly decreased, while the adoption and notification of the standardisation request and the standards' drafting time have increased, although large variations exist between standards.

While the overall time to develop a harmonised standard has decreased since 2012 (from an average of ten to six years, see Table 4), it remains too long to meet current market and legislative needs. The public consultation showed mixed views between stakeholder groups on whether the Regulation fully succeeded in reducing the standard-development time (44% disagreed; 40% agreed). Industry stakeholders and Annex III organisations are relatively dissatisfied about the timelines (see Figure 4 below). In the targeted consultation, only a small percentage of industry stakeholders (4% strongly agree, 16% agree) considers the current process to develop harmonised standards efficient[87]. The consultations showed different levels of dissatisfaction among sectors, with the manufacturing sector being the most dissatisfied.

Figure 4: Public consultation results on the level of satisfaction of stakeholders with time to develop standards

[86] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.1
[87] Targeted Survey Industry Q9: To what extent are you satisfied with the time needed to develop harmonised standards? Sample size: N = 50, Synopsis report, see Annex V



Source: Public consultation. N=253

Stakeholders particularly question whether the current timelines (1) allow timely implementation in relevant industries, (2) provide ample time for clear communication and preparation for implementation, and (3) are reasonable for industry stakeholders[88]. According to the evaluation study, in areas such as the timeliness for industry implementation and the reasonableness of timelines for standardisation requests, international companies show a greater tendency to disagree or strongly disagree with the process.

Harmonised standards can be needed by industry well ahead of the implementation deadlines set by sectoral or secondary legislation. The evaluation study assessed for 52 pieces of legislation the duration between the date of publication of the reference to the harmonised standard in the Official Journal of the European Union and the date when the respective harmonised legislation starts producing effects, considering both the date of application and the transposition deadline, when available. This assessment is based on certain assumptions but has significant limitations[89]. Nevertheless, it shows that the first harmonised standard may be published after the date of applicability or the transposition deadline of the respective law. The variance is very high depending on the legislation considered: in some cases, the first harmonised standard is published well in advance, while in other cases the first harmonised standard is published years afterwards. While this was not always a problem in specific transitions between old and new pieces of EU legislation, it led to legal uncertainty in other cases. For instance, in the case of unmanned aircraft systems, eight harmonised standards were requested to cover new legal requirements[90], for which the transition period ended on 31 December 2023. Only one was available in time, yet was cited with restrictions due to quality issues, and the other harmonised standards have remained pending, hence manufacturers have been obliged for a significant period of time to resort to other ways to demonstrate conformity. In the case of the cybersecurity requirements under the Radio

[88] Only 26% agreed or strongly agreed that standards are developed in a timeframe that allows timely implementation in relevant industries; only 35% agreed that the duration of the development process provides ample time for clear communication and preparation for implementation; only 30% agree that the timelines for standardisation requests are reasonable for industry stakeholders; Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.1.1

[89] While one legislation can be linked to many standard references, the evaluation study used the first published standard as a proxy to capture the "capability" of the standardisation system to deliver presumption of conformity in time. In addition, the evaluation study used the date of application only when it applies to the whole legal text (rather than certain parts of the legislation). The analysis did not fully take into account the applicability of existing standards. More details on the assumptions and limitations of the assessment are provided in Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Annex II Section 6.3.9.

[90] Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems; see case study in Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Annex VII

Equipment Directive, the date of applicability of the essential requirements had to be postponed to allow the ESOs to draft the three underpinning harmonised standards[91].

Whenever harmonised standards were delivered after the date of application, the stakeholders raised that the standard-development timelines did not allow for a timely implementation of the legislation by industry.

These timelines are in general relatively long compared to targets set by international standardisation bodies of third countries. For example, for ASTM International "*the average time for the development of a new standard is 18 months. Revisions to existing standards can be approved in six months or less"*[92]. For the Institute of Electrical and Electronics Engineers (IEEE), the *IEEE: 802.11* standards on wireless local area underwent almost one review per year[93], while the European EN 301 893 was updated nine times in 21 years (with the last update seven years ago)[94]. Some industrial consortia have an overall timeframe of circa 30 weeks, from the preparation (4 weeks), planning (10 weeks), development and release (15 weeks)[95].

The China National Standardisation Development Outline of 2021 sets a target development time for standards of 18 months. Since, newly established domestic standards-development organisations have developed their first standards within these timeframes, for instance on green computing, IoT and ultra-high-definition video technology[96]. In March 2024, the Chinese government issued its Action Plan for the implementation of the National Standardisation Development Outline to *"further improve the efficiency of national standard formulation and revision, achieving an average development duration of newly initiated national standards shortened to less than 18 months"*[97]. It is important to note that these other standardisation processes may not have a comparable level of consensus-making and/or stakeholder inclusiveness nor the same procedural steps like in the EU standard-development process. Other countries, such as the United States and Japan, do not have government-mandated standards and have not set overall target development times, yet there is a broad recognition of the need to accelerate[98]. Further details on standardisation processes in support of public policy in China, Japan and the United States are provided in Annex X.

Overall, the evaluation study revealed different reasons for the long duration of the different stages of the process: (i) the need to reconcile speed with full inclusiveness in the ESOs' drafting phase, which has reached a plateau between 2.5 and 3.5 years, (ii) the impact of case law on time taken for the OJEU publication, (iii) increasing pressure of legislation on deadlines and on

[91] Commission Delegated Regulation (EU) 2023/2444 of 20 July 2023 amending Delegated Regulation (EU) 2022/30 as regards the date of application of the essential requirements for radio equipment and correcting that Regulation

[92] ASTM International, *What to Expect as a Consumer Participant*, https://www.astm.org/get-involved/consumer-participation/what-to-expect.html

[93] IEEE 802.11 Working Group, *IEEE 802.11 Wireless LAN Working Group*, https://www.ieee802.org/11/

[94] Cf. ETSI, https://www.etsi.org/standards#page=1&search=301%20893&title=0&etsiNumber=1&content=0&version=1&onApproval=1&published=1&withdrawn=1&historical=1&isCurrent=1&superseded=1&startDate=1988-01-15&endDate=2024-11-04&harmonized=0&keyword=&TB=&stdType=&frequency=&mandate=&collection=&sort=1

[95] Catena-X, https://catenax-ev.github.io/docs/next/working-model/release-management

[96] Green Computing Consortium, https://en.opengcc.org.cn/ ; Global Intelligent Internet of Things Consortium, https://www.giiconsortium.org/ ; UHD World Association, https://www.theuwa.com/

[97] Standardization Administration of China (2024) Action Plan of Implementing National Standardisation Development Outline (2024-2025)

[98] For instance, the United States government announced that it *"will work closely with the private sector and academia to […] work collectively to address challenges to accelerate standards development in critical and emerging technologies"*, see United States Government National Standards Strategy for Critical and Emerging Technology, May 2023

capabilities of ESOs to deliver on time, (iv) communication and coordination problems among stakeholders, including HAS consultants, and (v) insufficient allocation of resources (such as funding, personnel, or information)[99]. In addition, in relation to the impact of case law, the significant number of negative quality assessments of draft standards (as part of the Commission's safeguard and control mechanisms put in place as a result of jurisprudence) can significantly prolong the process.

Prioritisation of key standards by the Commission has been improved in recent years. The publication of the AUWP has increased transparency on upcoming standardisation requests. In addition, digital standardisation needs are identified through the Commission's 'Rolling Plan for ICT Standardisation'. The AUWP and its priorities are considered clear and relevant by most NSBs/NCs/NSOs[100]. Representatives of industry associations instead express less interest or awareness in the contents of the AUWP and would like to be more engaged in the process. Since 2023, the European Commission has specifically requested inputs from stakeholders through the High-Level Forum on European Standardisation (HLF) on the AUWP and its priorities. Nevertheless, as shown in Section 3 above, there is a lack of timely response by the European Standardisation System to the standardisation priorities set out in the AUWP: even when the Commission announces standardisation priorities, which have been validated by stakeholders in the HLF and allocates dedicated funding through action grants to these topics, many initiatives remain[101]. This shows that the Regulation lacks effectiveness in delivering standards responding to EU policy priorities in a timely manner, in particular in new technology areas.

With regard to the different phases of the process, the accompanying evaluation study suggests that the longer duration of the submission of the standardisation request (phase A) may result from prolonged negotiations between the Commission and the ESOs, especially in case of complex standards and attributed to the new role of standards addressing more societal aspects (e.g. fundamental rights like in AI). In addition, while there can be a deadline for the delivery of standards by ESOs, the Regulation lacks a mechanism to set a defined duration of this phase.

Challenges in the drafting phase (phase B) that can delay the process include difficulties in reaching consensus, gaps in technical knowledge within ESOs in certain industries, and a lack of experts. Stakeholders also report challenges to incentivise companies to participate actively in the technical work, as well as an insufficient allocation of resources within the system[102].

In the submission and publication phase (phase C), quality issues can trigger significant delays, as illustrated by various case studies in the evaluation study[103]. Legal and procedural developments emerging from the jurisprudence (notably the James Elliott judgment), reinforcing the Commission's responsibility to thoroughly assess the compliance of draft standards, have added more administrative burden both within the technical committees of the European

[99] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.1

[100] In the targeted survey for NSBs (N=22), the wide majority respondents confirms, with no specific disagreement, the (i) ease of access of the AUWP (100%), (ii) the use of the AUWP for their own needs (90%), and (iii) the clarity of the AUWP with regard to the strategic priorities of the EC (90%). See Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.6

[101] In 2022, only one out of eight priority areas elicited a response; in 2023, responses were received for only three out of nine priority areas.

[102] Reported by 60% of industry stakeholders responding to the questions in the targeted consultation on speed of harmonised standard development in the targeted consultation. See Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.1.2.

[103] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Annex VII, case studies on pyrotechnics and drones

standardisation organisations and on the European Commission. A majority of respondents in the public consultation (58%) find the Commission's requirements to allow the citation of harmonised standards to be too burdensome[104].

With regard to the role of the ESOs and national standardisation bodies, while their business models may vary significantly (see box below), there is overall a strong incentive for all ESOs to respond to standardisation requests and for national standardisation bodies to participate in the work due to the high intrinsic relevance of harmonised standards (with harmonised standards being widely used by industry to demonstrate compliance with binding requirements). Direct costs for the ESOs and national standardisation bodies to lead the development of harmonised standards are to a large extent offset by the EU financing (see Section 4.1.2 below) and are therefore not considered a barrier. Yet, despite the intrinsic relevance of harmonised standards, the ESOs remain dependent on the willingness of stakeholders to contribute to speedy standard-development, which may vary between standardisation areas. Furthermore, with the Regulation only allowing standardisation requests to be addressed at the three ESOs (and not allowing the Commission to address the requests to other organisations that may be able to deliver faster), ESOs may need further incentives to adapt or accelerate their ways of working. For instance, while progress has been made on the use of ICT tools[105], including within the ESOs and NSBs, there is scope for substantial improvement. Standards are still delivered in PDF instead of in an editable digital format, unlike many open source or non-formal standards-development organisations. Commenting and editing processes often still rely on old methodologies: this takes time and makes certain 'roles' in standards-development (such as the role of rapporteur or editor) less attractive to stakeholders, in comparison with other standards-development organisations that use more interactive, online and open procedures. Digitalisation across the whole standards-development life cycle, but also with regard to the usability of standards, will be essential to be in line with a digital-by-default approach that the EU promotes to reduce administrative burden.

4.1.1.2. Ensuring representation of SMEs and societal stakeholders

The Regulation has provided a framework for stakeholder participation in the standards-development process, which has led to improvements.

In the targeted consultations underpinning the evaluation, representatives from large companies largely consider stakeholder participation in the ESOs to be effective[106], although some call for increased involvement in the Commission's planning process for new standardisation requests.

With regard to SMEs and societal stakeholders, the Regulation introduced the concept of Annex III organisations, which have been involved in the work of the ESOs in different ways (see Section 3 above). However, despite the increased intensity of their involvement, Annex III organisations do not always perceive their participation as leading to effective results. Moreover,

[105] In targeted industry consultations, 62% of respondents underlined improvements in the ICT tools used by ESOs in the delivery process of standardisation, while 58% of respondents underlined improvements in the ICT tools used by NSBs (e.g. online commenting platforms, online authoring platform, website accessibility, availability of virtual meetings, access to the working documentation of technical bodies), see Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.1.2

[106] 80% of industrial stakeholders responding to the targeted consultation (N=50) agreed that their organisation's participation in the work ESOs allowed them to contribute to technical work required in the standardisation process, while 74% considered that they are able to contribute significantly to the development and implementation of standards, see Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.1

they consider fragmented participation at national level to be detrimental to their impact at EU level. Effective participation of societal stakeholders in international standardisation also remains very challenging.

Both for Annex III organisations and for SMEs access costs are considered a major barrier. The evaluation study shows that participation requires significant financial efforts, which may be relatively more prohibitive for civil society and small businesses than for large companies (see efficiency section below). No positive developments were detected in this regard in the consultations. According to the public consultation, low engagement of SMEs and societal stakeholders is attributed to the process to engage or participate being too complex (65%), too costly (80%) and too time-consuming (84%)[107]. EU funding for Annex III organisations has gradually increased over the past years (see Section 3.1.2, Figure 2 above), yet the scope of their work has also expanded, as new technology areas become subject to harmonised standards.

Comprehensive data on participation in technical committees and working groups per stakeholder group is lacking, as this is not adequately covered by existing monitoring and reporting arrangements for ESOs and NSBs. However, anecdotal data shows that stakeholder participation varies between technical committees, depending on the sector and the topic. For instance, CEN-CENELEC's joint technical committee on artificial intelligence (JTC 21[108]), which covers the work of 5 different working groups, has seen participation of at least 65 different organisations. However, some large companies have multiple representatives participating through different national delegations, with for instance one multinational having 6 delegates through 5 national delegations. To date, it is also impossible to ascertain whether the same interests are represented through consultants who are accounted as micro-enterprises or SMEs. As a second example, CEN's technical committee on lifts, escalators and moving walks (TC 10[109]) covers 11 active working groups, with an estimated 55 experts involved in the TC and again with some large companies having multiple representatives through different national delegations. This can make it more difficult for smaller companies to have their voice heard in a similar way. The lists of represented organisations and interests in the committees and working groups are not always publicly available, resulting in a lack of transparency on the exact stakeholder balance.

Challenges also remain to ensure that the right societal stakeholders can participate in the process. For example, in the development of harmonised standards in support of the AI Act, some stakeholders consider expertise on fundamental rights to be lacking. Furthermore, despite the Regulation recognising the importance of representation and participation of people with disabilities in the standardisation process[110], people with disabilities and their representatives (Disabled Persons Organisations, DPOs) face structural barriers, such as financial barriers, a lack

[107] This includes replies "Agree" or "Strongly agree" to the question: "Why do you believe these groups are not effectively engaged or do not effectively participate?", N=83, see Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.1

[108] CEN/CLC/JTC 21 structure, https://standards.cencenelec.eu/dyn/www/f?p=205:22:0::::FSP_ORG_ID,FSP_LANG_ID:2916257,25&cs=1827B89DA69577BF3631EE2B6070F207D

[109] CEN/TC 10 structure, https://standards.cencenelec.eu/dyn/www/f?p=205:29:0::::FSP_ORG_ID,FSP_LANG_ID:5994,25&cs=16FE6EF2CDF1BCAF9DD443B75213B1A07

[110] Regulation (EU) No 1025/2012, recital 24: "The European standardisation system should also fully take into account the United Nations Convention on the Rights of Persons with Disabilities. It is therefore important that organisations representing the interests of consumers sufficiently represent and include the interests of people with disabilities. In addition, the participation of people with disabilities in the standardisation process should be facilitated by all available means."

of accessibility in procedures, documents or meetings, a lack of adequate accommodation for participation in technical bodies, and lack of consideration or voting rights of DPOs[111].

Regarding effective representation of research centres and universities, the evaluation study outlines various activities by ESOs to facilitate the engagement of the research community[112]. However, views in the public consultation are mixed, 43% of respondents agreeing that the Regulation has successfully ensured the participation of researchers and academics and 41% not knowing how to reply or neither agreeing nor disagreeing. Nine out of twelve research organisations responding to the public consultation indicated that the Regulation has not been sufficient in ensuring the participation of researchers and academics. Interviews with researchers show that costs related to access to standards or fees are a barrier for most researchers, while universities allocate low travel budgets for standardisation activities[113]. At the same time, researchers lack professional incentives and recognition for standardisation work. The Regulation has not succeeded in addressing these challenges related to costs and incentive structures for researchers and research organisations to participate in standardisation. Consequently, the voice of academics in ESOs and NSBs may not be sufficiently heard in comparison with larger industrial stakeholders, which bear the costs of participation more easily.

Stakeholder participation at the national level is encouraged by the majority of NSBs/NCs/NSOs, but there are significant challenges regarding the achievement of the real inclusiveness of societal stakeholders as well as relevant public authorities[114]. Despite certain support and awareness-raising actions, SMEs face financial challenges and lack technical expertise in standardisation. Barriers also remain for societal stakeholders and public authorities, as not all NSBs/NCs/NSOs have applied the best practices for engagement with these stakeholders.

A dedicated working group under the High-Level Forum on European standardisation assessed how SME access to national NSBs can be improved[115]. Several problems were identified, including required membership fees in many national standardisation bodies/committees and the large amount of time needed to invest into standards-development (roughly 25-30 working days per year depending on the area).

Overall, in terms of root causes underpinning the inadequate participation of certain stakeholder groups, the research and consultations show that various issues are at play. First, governance models of ESOs and NSBs have played a role, such as the uneven voting power allocated to certain corporate interests in ETSI (as highlighted in the 2022 EU Standardisation Strategy) or the lack of voting rights for certain societal stakeholders (notably Disabled Persons Organisations). Second, the complexity and long duration of the process and the associated cost of participation (as described in Section 4.1.1.1 above) can prevent effective involvement of small organisations. Accelerated and more digitised processes (for instance taking inspiration from open-source standard development methods) could make involvement of small organisations more affordable. Third, although a significant number of harmonised standards are

[111] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.1
[112] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.3
[113] Ibid.
[114] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.2.4
[115] High-Level Forum on European standardisation (2024) NSBs peer-review (including SMEs and civil society inclusiveness), Recommendations on national inclusiveness, https://ec.europa.eu/docsroom/documents/61794

based on international standards, there is no structural approach to promote the effective participation of underrepresented EU stakeholders in international standardisation organisations. Last, underrepresented organisations need the awareness and skills to participate effectively. Industry associations indicated in interviews that there is a need for action on education about standardisation and standards. With an ageing population of standardisation experts[116], it may be particularly challenging for small organisations to engage the right expertise needed for effective participation in technical committees. Members of the High-Level Forum on European Standardisation signed a pledge on education and skills in standards in November 2023[117].

4.1.1.3. Broadening the use of ICT "fora and consortia standards"

The process of identifying and broadening the use of common ICT technical specifications in public procurement has delivered only until it was stopped in 2017. The evaluation study identified (i) low interest by public authorities in participating in the identification process, (ii) increasing reliance on the traditional standardisation process (according to Article 10 of the Regulation) for ICT standardisation and (iii) a lack of data on the real use in public procurement as the main challenges hindering the effectiveness of this part of the Regulation. With the adoption of new legislation regulating emerging technologies (data, cybersecurity, AI, etc.), an increasing range of ICT-relevant standardisation falls under the scope of Article 10 of the Regulation. In 2024, the Multi-stakeholder platform on ICT standardisation announced that it would resume the identification process of ICT specifications related to the eIDAS Regulation[118].

Three other issues in the field of ICT standardisation emerging from the evaluation study are (1) the role of big technology companies in creating *de facto* standards that may undermine interoperability; (2) the lack of 'software' knowledge in technical committees; and (3) the important role of open standards as more companies rely on open-source projects[119].

4.1.1.4. Removing ambiguities in the legal framework

The accompanying evaluation study showed that the Regulation has improved the alignment of national and European standards, with overall transposition rates reaching on average 86% of active ENs transposed into national standards in all EU Member States. However, for ETSI NSOs, the share of active European standards implemented by all EU Member States remains below 50%.

With regard to the formal objection procedure (Article 11; see details in Section 3 above), this instrument has only been used 41 times since 2014. This may reflect the effectiveness of the compliance checks on draft harmonised standards by the Commission in line with Article 10 (6).

However, when formal objections are invoked, the mechanism functions very slowly requiring on average 21 months, which creates significant uncertainty for stakeholders. In interviews

[116] The 2024 European Standardisation Panel Survey shows that only 38% of current experts involved in standardisation are aged 49 years or younger, and hence that 62% are 50 years or older. It is expected that a quarter of the current pool of experts needs to be replaced by 2030. See European Commission, Directorate-General for Research and Innovation, Blind, K., Baldan, F., Tardos, G. et al., European standardisation panel survey – Final report, Baldan, F.(editor), Tardos, G.(editor), Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/643814

[117] https://single-market-economy.ec.europa.eu/document/22c13ff4-1dd2-4e6d-9475-71d13324a3b9_en

[118] Regulation (EU) 2024/1183 of the European Parliament and of the Council of 11 April 2024 amending Regulation (EU) No 910/2014 as regards establishing the European Digital Identity Framework

[119] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.3

underpinning the evaluation study, industry stakeholders indicated that they would prefer an earlier dialogue with public authorities or market surveillance authorities to address possible legal compliance issues with harmonised standards.

4.1.1.5. Broader impacts

Functioning of the internal market

European and harmonised standards have had a positive impact on the EU Single Market, contributing to trade and supporting global value chains in Europe[120]. They have also helped build trust between companies and customers, facilitate communication, and lower technical trade barriers[121]. Industry stakeholders indicate that prior to the entry into force of the Regulation, trade in the internal market was more challenging due to the prevalence of national standards.

Nevertheless, businesses do indicate that they sometimes face challenges in the use of harmonised standards (supporting EU legislation) and therefore choose not to use them. These challenges include difficulties in identifying the relevant standard without buying it first, and European standards not keeping up with emerging market trends in a timely manner[122]. These issues hamper the positive impact of harmonised standards on the Single Market.

Competitiveness, growth and innovation

Evidence from studies and targeted consultations underpinning the evaluation show that standards moderately contribute to facilitating growth, innovation and increasing competitiveness of European businesses, especially for SMEs, but their effectiveness varies and depends on the sector. First, harmonised standards do not immediately result in growth, but they reduce production and compliance costs and have an effect in the long run[123]. Second, standards are generally considered to foster innovation in products and services[124]. The industry survey shows that a majority of stakeholders agrees (28%) or strongly agrees (30%) that harmonised standards facilitate the market penetration of innovative technologies, yet there is a noticeable share of respondents who are neutral (26% neither agree nor disagree)[125]. This split can be explained by the fact that standards are typically drafted taking into account the state-of-the-art and existing performance. Producing standards that completely anticipate future products, needs or use cases can be very challenging, unless sufficient and consistent pre-normative research and standardisation have been carried out so to support the deployment of new technologies. Third, the direct impact of harmonised standards on competitiveness is unclear, with industry surveys revealing mixed views[126].

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[120] Blind, K., Mangelsdorf, A., Niebel, C., & Ramel, F., Standards in the global value chains of the European Single Market. Review of International Political Economy, 2018, pp. 28–48. https://doi.org/10.1080/09692290.2017.1402804

[121] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, 2021b, https://ec.europa.eu/docsroom/documents/50114

[122] Ibid.

[123] Question 35 "Do harmonised standards contribute effectively to enhancing the effectiveness of European business within the Single Market" in the targeted survey of industry associations and companies (N=50): 40% strongly agreed and 32% agreed, whereas 12% were neutral in replying whether harmonised standards reduce the production costs for companies.

[124] Blind K, Krieger B, Pellens M (2022) 'The interplay between product innovation, publishing, patenting and developing standards', *Research Policy*, Volume 51, Issue 7, https://doi.org/10.1016/j.respol.2022.104556

[125] N=50. See details in Annex V.

[126] Industry responses on the impact of harmonised standards on competitiveness (N=50) vary, with strong agreement accounting for 24% and agreement for 30% of the responses, while 32% remained neutral, indicating that clear evidence may be lacking. See Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.5, as well as the Synopsis report in Annex V.

Academic research shows that standards have several functions that can contribute to economic growth and competitiveness[127,128,129]. First, they codify technological know-how and make it available to companies. Information about the implementation of standards can reduce information asymmetries between the supply and demand side and therefore increase market efficiency. Second, the implementation of standards can reduce operational costs by establishing procedures that lower expenses for repeated activities. Third, interoperability standards can help facilitate network externalities as an increasing number of users can enhance the value of technologies and products. Fourth, standards can create trust among customers (in particular related to the quality of a product) and promote the commercial success of a specific category of products.

Studies[130,131] also found an increase in the stock of standards to be positively correlated with economic growth, measured by Gross Domestic Product (GDP), labour productivity or Gross Value Added (GVA). In particular, an increase of 1% in the stock of available standards is expected to contribute from 0.2% to 1% of GDP growth at national level[132].

While comprehensive data on the sectoral impact of harmonised standards on competitiveness is missing, several evaluations of sectoral legislation report relevant data on the contributions of standards in regulated sectors of the EU economy, mainly through a reduction of compliance costs. However, the competitive edge gained through the use of harmonised standards diminishes when cost reductions are uniform across companies[133].

One particular competitiveness-related benefit is that the use of harmonised standards by businesses can provide a presumption of conformity, thereby helping businesses save costs by avoiding the need for a third-party conformity assessment. A quantification of these cost savings is often lacking in sectoral evaluations, yet the 2017 impact assessment of the New Legislative Framework[134] reports that *"the annual budget of firms for services of Notified Bodies is in the range of EUR 30 - 80k, around €4,000 for certification of a single product and representing 20-25% of the total estimated costs for compliance"*. Annual certification of systems would be more costly. Additionally, in terms of certification costs (excluding costs for technical documentation and labelling), the 2023 impact assessment of the revision of the Toy Safety Directive reports an estimated average of EUR 500 per new toy model in case of self-certification and EUR 1 000 in

[127] Swann, G., International standards and trade: A review of the empirical literature, OECD Trade Policy Papers No. 97, OECD Publishing, Paris, 2010, https://doi.org/10.1787/5kmdbg9xktwg-en

[128] Blind, K. (2004): The economics of standards theory, evidence, policy. Cheltenham, UK et al. Elgar.

[129] Blind, K. (2024): Standardization in the context of transdisciplinarity. Sustain Sci 19, 1609–1621 (2024). https://doi.org/10.1007/s11625-024-01524-3.

[130] European Commission (2022): Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, https://ec.europa.eu/docsroom/docu-ments/50114

[131] 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

[132] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.5.2

[133] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.5.2

[134] Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

case of third-party conformity assessment[135] plus the costs of the internal production controls[136]. Certification costs are likely to be significantly higher for more complex products.

Beyond enabling a presumption of conformity, the evaluation of the Pressure Equipment Directive[137] revealed further economic and technical advantages from the use of harmonised standards. These include lower costs for in-service inspection and maintenance, reduced material and manufacturing costs (compared to other specifications), and a prolonged product life expectancy (deferring replacement costs). Besides cost savings, the regulatory simplification driven by harmonised standards can also be a key factor in fostering market growth and boosting competitiveness.

Several other evaluations (i.e. those covering hazardous substances in electrical and electronic equipment[138], construction products[139], and the lift directive) report that the implementation of harmonised standards has contributed to create a consistent regulatory framework across different product categories.

Moreover, the sectoral evaluations report that once the CE marking is applied on the basis of compliance with harmonised standards, national testing and certification processes are no longer required, reducing compliance costs and, more significantly, alleviating the administrative burden associated with regulatory adherence. This ensures the smooth operation of the internal market and facilitates economies of scale across various sectors.

Finally, according to the evaluations, harmonised standards offer the benefit of establishing mechanisms for coordination among Notified Bodies and Market Surveillance Authorities. This encourages regular engagement with peer entities and the European Commission, enhancing regulatory oversight and promoting consistent enforcement of standards across the EU.

When comparing the difference between harmonised standards (subject to the Regulation) and other European standards in terms of impact on innovation, the study results vary. The overall findings show that harmonised standards are largely seen as beneficial for innovative technologies. Yet, as harmonised standards reflect legal requirements, some stakeholders believe that purely industry-driven standards are able to better foster innovation.

At the same time, other stakeholders suggest that businesses sometimes seek to block innovation in order to maintain their competitive edge[140]. Strict technological neutrality and strong consideration of balanced stakeholder participation in the development of harmonised standards may avoid such negative impacts on innovation.

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[135] Staff Working Document, Impact assessment report accompanying the document proposal for a Regulation on the safety of toys and repealing Directive 2009/48/EC Toy Safety Regulation, SWD(2023) 269 final

[136] Internal production controls are part of Module C of a conformity assessment, as outlined in Decision 768/2008/EC. In the absence of a presumption of conformity from a harmonised standard, such internal production controls must be undertaken in addition to the third-party certification.

[137] Centre for Strategy & Evaluation Services, Evaluation of the Pressure Equipment Directive (PED) 2014/68/EU, October 2012, https://op.europa.eu/en/publication-detail/-/publication/f2eec648-0f73-48a7-875b-8d4b3934cb2b

[138] Staff Working Document,,Evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

[139] Staff Working Document, Evaluation of Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, SWD (2019) 1770

[140] Idem

Survey data from the evaluation study reveals that inefficiencies in the standard-development process (as described in previous sections) may hinder the Regulation's effectiveness in enhancing competitiveness in the Single Market[141]. This includes concerns related to (1) European standards being outdated and no longer reflecting state-of-the-art, (2) a lack of harmonised standards for specific regulations (such as medical devices), (3) procedural challenges preventing adequate revisions of standards (notably in the construction sector), and (4) misalignment with industry needs (for instance with standards failing to reflect technological advancements). In particular, the late delivery of harmonised standards (after the date of application of new legislation) can have significant cost implications for businesses, as they cannot benefit from cost savings related to the presumption of conformity and may be obliged to engage third-party conformity assessment. In addition, for innovative SMEs and startups, the challenges to participate in the standardisation process (related to the long duration and complexity of the standardisation process and the costs of participation, as described in Section 4.1.2 below) may give a competitive advantage to larger incumbents.

Social and environmental impacts

Regarding social and environmental impacts, European standards are widely seen as contributing to environmental protection, as they help companies demonstrate compliance with environmental regulations, with 68% agreement across sectors[142]. According to a 2023 study, stakeholders also consider harmonised standards to contribute to achieving the United Nations' Sustainable Development Goals (SDGs), although they also see a scope for improvement and suggest *"adapting standard-setting processes to more concretely consider SDGs, increasing diversity in standard-setting committees […] and improving coordination between different areas of standardisation, as well as international harmonisation"*[143]. Most companies also consider standards to contribute to promoting health and safety and consumer protection. These effects are generally achieved indirectly through the essential requirements set by environmental, consumer protection and sectoral legislation.

4.1.1.6. Conclusions on effectiveness

Although certain steps of the process have improved and accelerated, the European standards-development process generally remains lengthy and complex, with a total average duration of six years. This remains too long to meet legislative and market needs (see further assessment under relevance in Section 4.3 below). Efforts have been made to prioritise urgent standardisation needs (notably through a new prioritisation in the Annual Union Work Programme for European standardisation), yet the European standardisation system often fails to tackle these priorities in a timely manner.

Root causes include the procedural bottlenecks, the need to reconcile speed with full inclusiveness in the ESOs' drafting phase, quality issues in draft standards combined with the new safeguards and control mechanisms put in place as a result of jurisprudence, increasing pressure of legislation and market needs on capabilities of ESOs to deliver on time,

[141] Idem

[142] European Commission and EY, Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24) – Final report, Publications Office, Luxembourg, 2021a, p. 7, https://data.europa.eu/doi/10.2873/504681

[143] Blind, K., & Heß, P., Stakeholder perceptions of the role of standards for addressing the sustainable development goals. Sustainable Production and Consumption, 2023, pp. 180–190. https://doi.org/10.1016/j.spc.2023.02.016

communication and coordination problems, and insufficient allocation of resources. With the Regulation only allowing standardisation requests to be addressed at the three ESOs (and not allowing the Commission to address the requests to other organisations), the current framework lacks flexibility and ESOs may need to be incentivised further to adapt or accelerate their ways of working.

Stakeholder representation has improved under the Regulation, yet standardisation processes are still too complex, costly and time-consuming for SMEs, academia and societal stakeholders to participate effectively. The introduction of the concept of Annex III organisations has been a positive development, yet Annex III organisations do not always perceive their participation as leading to effective results. Root causes include the long duration of processes and the associated cost of participation, governance models of ESOs and NSBs, and a lack of awareness and skills in standardisation among underrepresented organisations. Detailed data on participation in technical committees and working groups per stakeholder group is lacking, which suggests that existing monitoring arrangements for ESOs and NSBs do not allow for an in-depth analysis of the evolution of stakeholder participation. Accessibility challenges in the standardisation process, notably for people with disabilities or other societal stakeholders that EU legislation affects, also remain in many cases unaddressed. The alignment of national and European standards has improved under the Regulation.

With regard to ICT technical specifications, while the use of identified common ICT specifications can result in improved effectiveness in public procurement, the identification process established in the Regulation has delivered only until it was stopped in 2017[144]. This was counterbalanced by to the adoption of digital-specific legislation over the past ten years, such as the AI Act or the Data Act[145].

Broader impacts of harmonised standards on competitiveness are difficult to assess, yet are considered to be positive in terms of general impact on growth (as measured by Gross Domestic Product, labour productivity or Gross Value Added), cost savings for businesses and innovation (by promoting the codification and sharing of know-how). The legal value of harmonised standards (as opposed to other standards) provides specific benefits to businesses in terms of legal certainty and cost savings (linked to the presumption of conformity and avoiding the need for costly third-party conformity assessments). However, inefficiencies in the standard-development process can hamper these impacts.

4.1.2. Efficiency

The evaluation assessed the direct and indirect compliance costs and benefits for key actors in the development process for standards. The data limitations need to be recognised in particular for this section.

There is little literature as to the costs and benefits of standardisation for stakeholders and society overall, which would be based on quantitative data and could be verified. In various stakeholder

[144] At the end of 2024, it was announced that the identification of ICT specifications would resume in support of Regulation (EU) 2024/1183. This falls outside the temporal scope of this evaluation.
[145] Regulation (EU) 2024/1689 and Regulation (EU) 2023/2854

consultations, including targeted outreach as part of the evaluation study, little evidence was obtained.

There is no information available on the costs associated to purchasing or subscription for standards. In the process of collecting information for the accompanying study no relevant literature was identified and no hard data has been collected. The impact assessment[146] attempted to estimate the costs borne by businesses, but the methodology used was based on strong assumptions and provided mostly qualitative findings. Moreover, previous monitoring exercises have not attempted to quantify costs. As a result, there was a lack of a clear and robust baseline to rely on, and primary data collection was fundamental.

For the reasons explained above, a mixed method approach was adopted, and the available evidence was triangulated to ensure the robustness of data through public consultation, targeted surveys and interviews.

The dissemination of the public consultation and of targeted surveys involved strong direct engagement with key EU stakeholders. In particular, the link to all the online questionnaires was shared in their respective internal network of contacts by the ESOs, among all its members, cross-sectoral EU business organisations, sectoral EU umbrella organisations, and SBS, the Annex III organisation representing SMEs in standards. Interviews were also used to triangulate the findings from the surveys.

In the targeted surveys, and during interviews, companies confirmed that it is very hard for them to find precise data collected on the costs linked to the Regulation (e.g. the cost to participate to technical committees, the annual costs borne to buy standards etc.). They do not record this type of data, and it is extremely complex for them to gather evidence at such a granular level. As a result, it is challenging for a single company to report on such costs. Thus, umbrella organisations were contacted to collect at least qualitative evidence on the costs associated to the Regulation. As a result, while the sample is not "statistically representative", the umbrella organisations represent a very large number of companies, and their feedback is considered to be in line with the expectations of the body of companies they represent.

During the individual interviews with companies, a wide sectoral coverage was achieved by the study team. In addition, to ensure that the multiple sectoral perspectives are taken into account, in-depth interviews were conducted with EU cross-sectoral organisations representing several EU industries, including Digital Europe, BusinessEurope, ORGALIM - Europe's Technology Industries of the EU market covered by EU harmonised standards.

4.1.2.1. Costs

Direct compliance costs

Direct compliance costs of the Regulation are the costs for stakeholders that are directly linked to the provisions of the Regulation and include adjustment and administrative costs, as follows:

[146] European Commission, Impact Assessment, accompanying document to the Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC, 2011, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2011:0671:FIN:EN:PDF

- Article 24 generates administrative costs for Annex III organisations and administrative costs for ESOs mainly due to reporting obligations.
- Article 3 and Article 4 generate administrative costs for ESOs and for National Standardisation Bodies, mainly due to reporting requirements.
- Article 6 generates administrative costs for National Standardisation Bodies.
- Articles 13 and 14 generate administrative costs of identifying common ICT technical specifications under the process established by Articles 13 and 14 of Regulation (EU) 1025/2012.
- Articles 8, 10 and 16 generate administrative costs for the European Commission, including due to reporting obligations.

There are difficulties with the application of a strict cost classification in line with Better Regulation requirements due to the specifics of the legislative instrument, but also due to existing data collection limitations. Direct costs (for the Commission, the ESOs, the NSBs and the Annex III organisations) not linked to administrative tasks (including reporting) may in theory be considered as adjustment costs, but an estimation of adjustment costs is only possible for the EC (the expenditure linked to the EU funding). It is important to note that the direct costs for the ESOs, the NSBs and the Annex III organisations are to a large extent offset by the EU financing.

Broken down per stakeholder group, the direct compliance costs can be summarised as follows for the European Commission, three ESOs, Annex III organisations and industry stakeholders.

European Commission

The European Commission's annual expenses in support of European standardisation are estimated to be circa EUR 31 million[147], including from the Single Market Programme and other programmes. This covers support to various entities and initiatives, including operating grants to the ESOs and Annex III organisations, action grants to ESOs for dedicated projects/policy areas, translation grants, expenses for the HAS consultants, IT (database management) support and other. These expenses can be considered adjustment costs mainly, as they are not linked to administrative tasks. The Joint Research Centre of the Commission spends an estimated EUR 30 million annually on activities related to standardisation. This includes work on pre-normative research, participation in technical discussions, research and development activities, outreach education activities, and supporting the Commission services in their standardisation policy work.

Furthermore, several EU funded programmes, such as the EU Framework Programme for Research and Innovation, the Connecting Europe Facility or the Digital Europe Programme, as well as Public and Private Partnerships have dedicated pilots and projects that contribute to standardisation. For example, the *6G Smart Networks and Services Joint Undertaking*[148] has systematically integrated standardisation-support into its projects. The third call of its research and innovation work programme dedicated to market deployment aims at contributing to 6G global standards-setting as a bridge between research/development to market

[147] This refers to the average value of the costs from 2021 to 2023.
[148] https://digital-strategy.ec.europa.eu/en/policies/smart-networks-and-services-joint-undertaking

deployment[149]. However, the pre-normative support through EU Financial Programmes is scattered and there are no consolidated figures of overall annual EU expenses for standardisation.

From 2014 to 2023, according to the supporting evaluation study, the costs for the European institutions have remained relatively stable with an increased compound annual growth rate of 6.5%[150], which is just above the 6% inflation rate. Expenses have particularly increased for IT support (17%) and for the Annex III organisations for environmental interests (15%) and social interests (14%).

As one of the simplification measures, the Regulation set out the objective of introducing lump sums to reduce administrative burden on the Commission and the European standardisation organisations. During the implementation period of the Regulation, substantial challenges were encountered in implementing lump sums: (i) high price variability, as it proved difficult to capture the complexity and associated costs of various standardisation activities in lump sums; (ii) risk of reducing the activity scope, as some activities proved to be more expansive, and some less expensive than accounted for within the lump sums; and (iii) inconsistency with the 'non-profit' rule, as the lump sums diverged too much with the actual costs incurred. Following extensive negotiations with the European standardisation organisations, lump sums were established for a limited scope of the financing between 2015 and 2020, namely for the development and revision of European standards and deliverables, as prescribed in Commission Decision C/2015/3697[151]. As such, the desired effect of lump sums was not efficient in the implementation of the Regulation.

The three European Standardisation Organisations (ESOs)

As presented in Section 2.1.2, CEN, CENELEC, and ETSI have distinct business models resulting in different funding approaches. CEN and CENELEC receive funding primarily through NSBs' and NCs' membership fees. Standards and deliverables are sold by national standardisation bodies. ETSI receives funding from its members that can be individual companies, government and public organisations, and other organisations globally. ETSI's standards are available free of charge for its members. During the implementation period of the Regulation, CEN and CENELEC have typically applied for and received more action grants than ETSI and worked on more standardisation requests. This had an impact on the related reporting costs, which are higher for CEN/CENELEC. The total annual administrative cost for all three ESOs combined is estimated by the study at EUR 527 000 in 2024[152].

On average, the evaluation study observes that costs have decreased at a compound annual growth rate of -6% from 2015 to 2024. This is mainly due to the decreased person-days needed for reporting on the implementation of the Regulation (Article 24) and on the financing of standardisation activities (Articles 15 and 17). In addition, the total person-days dedicated to administrative tasks, as well as to the annual reporting on the execution of a standardisation request have decreased.

National Standardisation Bodies

[149] SNS R&I Work Programme 2024, https://smart-networks.europa.eu/sns-ju-ri-work-programme-2024/
[150] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.2.1.1
[151] Commission Decision C/2015/3697
[152] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.2.

Data on direct costs for National Standardisation Bodies (NSBs/NCs/NSOs) was collected through the targeted survey carried out in the evaluation study. Costs data were provided by 19 National Standardisation Bodies (NSBs/NCs/NSOs), representing 55% of all such organisations.

The evaluation study estimated the total annual cost for all National Standardisation Bodies combined to be around EUR 2 million. The annual average cost for one National Standardisation Body is estimated between EUR 1 400 and EUR 123 000[153].

Targeted survey data indicate that National Standardisation Bodies may face administrative burdens, particularly with drafting work programmes[154]. However, NSBs did not comment on their proportionality. Moreover, there is no available historical data to trace the development of efficiency. Notably, there are variations in reported costs between NSBs, suggesting differences in sharing best practices and addressing comments. It is unclear if this is due to cost-efficient measures or more activities by some NSBs.

Annex III organisations

Annex III organisations reported data on administrative costs as part of the study on the implementation of Regulation (EU) No 1025/2012 (Article 24) conducted in 2021 and the study on the implementation of the Regulation conducted in 2015.[155] The total annual compliance costs for all four Annex III organisations combined is estimated at approximately EUR 228,500 in 2024. It should be noted that these costs are largely offset by EU financing. Interviews with Annex III organisations revealed that costs vary between the organisations, but they cannot be disclosed due to confidentiality reasons.

Costs have, on average, risen by 45% from 2015 to 2024 due to a greater amount of time required to complete some activities[156]. The time required to draft Article 24 Reports has been reduced by 8%. However, the preparation time for the action plan (i.e. work programme related to the operating grant) has increased by 23% from 2015 to 2020, and by 75% for the final and interim reporting. Interviews with Annex III organisations confirm an increase in burden related to reporting requirements and they attribute the increased costs to the higher level of detail required in the action plans.

Indirect compliance costs

The European standardisation involves many stakeholders, whose participation in standard-setting and use incurs certain costs. In contrast to the direct compliance (adjustment and administrative) costs, which result from obligations imposed on stakeholders by the Regulation, participation in standard-setting is an option. As such, participation costs may be considered

[153] Please see Annex II for more details on the methodology.
[154] The evaluation study estimated the total annual cost for all National Standardisation Bodies combined to be around EUR 2 million. The annual average cost for one National Standardisation Body is estimated between EUR 1 400 and EUR 123 000. See Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.2.1.1.
[155] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020, 2022, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2022:30:FIN
European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24) – Final report, Publications Office, Luxembourg, 2021a, https://data.europa.eu/doi/10.2873/504681
[156] These are calculated with 2020 and 2015 data points adjusted to inflation to ensure compatibility.

indirect costs of the Regulation[157]. The indirect costs include participation costs for the technical work to develop and revise standards incurred by Annex III organisations and by businesses, including SMEs, and the costs of purchasing harmonised standards incurred by businesses and other users.

Annex III organisations

Annex III organisations face costs for operations, member coordination, and dissemination. As previously explained, data limitations hampered a quantifiable collection of all estimated costs incurred by Annex III organisations for their participation in standardisation activities. They bear expenses for participating in technical work on European standards, as well as requiring legal and technical expertise. Union financing covers an estimated 80% to 90% of these costs but also rely on complementary funding from private philanthropic sources or membership fees. Interviews with Annex III organisations indicated that many technical experts often volunteer their time for technical work and that they may receive reimbursement for travel expenses or a daily allowance to cover accommodation and subsistence costs.

The evaluation study collected costs associated with participating in the technical work of harmonised standard setting using targeted surveys to Annex III organisations. Costs data was provided by all Annex III organisations. The annual average costs of participating in technical discussions for all four Annex III organisations combined is estimated at EUR 1.3 million, with average annual average cost for a single Annex III organisation between EUR 145 000 and EUR 984 000.[158] Caution must be taken when interpreting these data due to the diverse organisational and financial structures of Annex III organisations, different number of experts, and different number of TCs/WGs they participate in, which result in significant variations in costs. Annex III organisations reported an increasing workload given the adoption of new legislation that draws on harmonised standards as a deliverable tool.

As not-for-profit organisations representing societal interests, Annex III organisations and their members do not experience a direct monetary benefit from their participation in standardisation activities. However, the work in standards-development links to their overall mission as not-for-profit civil society or SME organisations, and manifests itself in the formal opinions that they issue on draft standards.

Businesses

Businesses engage in the development and revision of European standards and incur indirect compliance costs through the participation of their experts. There is a general lack of company-level data on such in-kind contributions to the standard-development process. Therefore, due to poor data availability, limited data collection in the study and high variability of data, caution is to be taken when interpreting the below findings on these costs.

[157] The concept of indirect costs used in this analysis slightly differs from the one provided in the Better Regulation Toolbox. The definition provided in the Toolbox refers to indirect compliance as costs that typically arise from adjustments in the prices, quantity, or quality of goods and services within the regulated sector. Regulation 1025/2012 sets out a framework for European standards requested by the Commission, thereby influencing the standardisation work. Participation in standardisation activities is voluntary, yet it requires significant investments from those who decide to participate. Therefore, it represents an important cost for those stakeholders. As a consequence, the study has classified these costs as indirect costs.

[158] The values are estimated using standard errors to determine the range within which the arithmetic mean is likely to fall. This is done by constructing a confidence interval. In this case this is done by using the Z-value of 1.96 corresponding to a 95% confidence level.

Businesses typically contribute in-kind to standards-development by sending experts to the technical committees (TCs) and conducting testing and laboratory work[159], but the study was unable to provide reliable cost estimates on the latter. Only the costs of participation in technical discussions could be estimated and modelled in four categories, with a methodology applied to account for labour, materials, and equipment for each of the following activities[160]:

A. Proposal and acceptance process of new work items
B. Participation in technical discussions on proposals
C. Submission of comments on draft standards or deliverables
D. Revision of existing European standards or deliverables

The annual average cost of participating in standardisation activities, including but not limited to those covered by the Regulation, for one standard for a single business is estimated to be between EUR 64 756 and EUR 160 687 for an SME, and between EUR 72 328 and EUR 331 469 for a large company[161]. At the lower end of the estimates, costs are similar regardless of business size. At the upper end of the estimates, costs are higher for large companies. The relatively similar lower-end cost estimates suggest that minimum-level participation costs in standardisation activities are rather uniform across business sizes, potentially making these activities relatively cost-intensive for SMEs (in relation to their turnover), which could limit their ability to participate. A 2021 study[162] estimated the cost of developing a European standard to be approximately between EUR 780 000 and EUR 1 000 000, while the cost of developing other standardisation deliverables was estimated to be between EUR 311 000 and EUR 389 000. This includes the in-kind contributions from companies and experts.

With regard to the total costs for all businesses participating in technical discussions within the European Standardisation System, there is some stakeholder reporting on in-kind contributions to standards-development, such as from the German association for the Electrotechnical and Digital Industry (ZVEI), which estimates an annual cost of EUR 300 million for German businesses in its sector[163]. However, total costs for EU businesses cannot be estimated due to missing data on the average number of businesses that participate in technical work.

The significant cost of participation in technical discussions is reflected in the large number of meetings. For instance, as an illustration of the broad scope of activities of one CEN TC, the technical committee on lifts, escalators and moving walks (TC 10), its related sub-committees and the 13 working groups met annually 74 times with a total duration of 111 days in 2023. During the last five years, this TC produced on average 4 standards per year[164]. Monitoring data reported by ESOs and NSBs does not allow for an analysis of the average number of meetings and participants per meeting across all technical committees.

[159] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, section 4.2.
[160] For the detailed methodology, see Annex II.
[161] For these estimates we used the confidence interval of the arithmetic mean computed with winsorised data. This is due to the sensitivity analysis for industry survey data, which indicates that the original data estimates are highly affected by outliers (especially for SMEs). Moreover, the Monte Carlo simulation suggests that the arithmetic mean of the winsorised data provides a more accurate estimate.
[162] Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, November 2021, European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. See paragraph 4.1.3.3.1, pp. 72-73
[163] ZVEI position paper, "Steuerliche Normungsförderung ermöglichen", https://www.zvei.org/
[164] CEN/TC 10, https://standards.cencenelec.eu/dyn/www/f?p=205:32:0::::FSP_ORG_ID,FSP_LANG_ID:5994,25&cs=16FE6EF2CDF1BCAF9DD443B75213B1A07

Businesses were asked in the targeted survey to provide the estimated costs of purchasing or subscribing to standards to estimate the costs of buying standards. Only 20 responses were received, which did not allow conducting a subgroup analysis by size of company. Overall, the costs for buying the standards vary significantly from company to company. Businesses that have a subscription to standards can spend from EUR 15 000 to EUR 500 000 a year. In contrast, businesses that buy standards without subscription can spend from EUR 90 to EUR 90 000 a year. The significant variation in costs can be attributed to differences in countries and sectors. Interviews with business associations revealed that the cost of purchasing or subscribing depends largely on the number of harmonised standards available for a specific sector. Additionally, prices can vary based on the technical content. Finally, prices are not uniformly set across national standardisation bodies.

It must be noted that ETSI makes its standards available for free in PDF format and charges a membership fee, as per their website[165]. Nevertheless, given that most ETSI standards contain several cross-references to standards of other organisations that may charge costs for their standards, using ETSI standards still comes at a cost for businesses, as they may have to purchase access to these additional standards to be able to apply the ETSI standards.

Opportunity costs

Opportunity costs refer to the cost associated with foregoing alternative investment options, and in the case of harmonised standards refer to compliance costs that would incur if harmonised standards were not in place, or if they are delayed. They include EU opportunity cost for conformity assessments relating to voluntary harmonised standards compared to other conformity assessment procedures, and global market opportunity costs for conformity assessments relating to using voluntary harmonised standards in the EU market compared to other conformity assessment procedures in third countries markets (e.g. type approval).

On the EU market, businesses face opportunity costs while awaiting the publication of harmonised standards in the Official Journal and are being prevented from using the presumption of conformity.

The costs for companies have been so far rarely quantified both in policy documents linked to harmonised sectoral legislation and in the literature. Moreover, it is important to notice that there is no evidence of such costs being recorded at company-level or industry organisation levels.

Only few documents report some quantitative data on the costs of running a third-party conformity assessment in the absence of a harmonised standard providing presumption of conformity, such as the impact assessment of the New Legislative Framework[166] and the impact assessment of the revision of the Toy Safety Directive[167].

[165] https://www.etsi.org/membership/dues

[166] According to the NLF impact assessment, a conformity assessment for a single product in gardening equipment manufacturing industry typically costs EUR 4 000 in Notified Bodies fees, though annual certification of systems would be much higher.

[167] This impact assessment reported an estimated average of EUR 4 000 per new toy model in case of self-certification (including EUR 500 for the self-assessment, EUR 2 800 for the technical documentation and EUR 700 for the labelling), and EUR 4 500 in case of third-party conformity assessment (including EUR 1000 for the third-party assessment and obtaining an examination certificate, EUR 2 800 for the technical documentation and EUR 700 for the labelling).

In view of this very limited evidence, the supporting evaluation study should be considered as the first systematic attempt to estimate this kind of costs for businesses.

Accordingly, approximation of these costs was collected through the targeted survey of businesses using stated preference techniques[168]. The application of the willingness to pay (WTP) shows that these potential costs can amount to EUR 3 700 per product. This estimate is close to the few data points in the Impact Assessments of the NLF and the Toy Safety Directive (around EUR 4 000 as reported above).

Stakeholder consultations in the study revealed that EU businesses largely benefit from harmonised standards, which significantly decreases their compliance costs. This is why businesses have a keen interest in speedy standards-development and the citation of harmonised standards in the Official Journal of the EU, as they otherwise face additional costs from relying on conformity assessment procedures at notified bodies. Hence, delays in citation provide an opportunity cost.

Based on the responses in the targeted survey for businesses, it appears that organisations are willing to pay for time reductions of the citation period. This implies that administrative procedures are perceived as costly and consequently confirms previous findings that reducing delays in the overall standards-development and citation processes is highly valued by industry and represents a cost that they would be willing to offset.

The targeted survey also collected data on the cost of using other conformity assessment procedures in third countries markets, covering Canada, China, South Korea, Japan, South Africa, and the United States, compared to using voluntary harmonised standards in the EU.

In the United States and China, the costs of placing products on the markets are higher, although the United States shows a less than one percent difference compared to EU related costs. In South Korea, Japan and South Africa, conformity assessment costs seem to be lower than in the EU.

4.1.2.2. Benefits

Direct regulatory benefits

Embedded in the New Legislative Framework, Regulation 1025/2012 is closely intertwined with sector-specific legislation that draws on the use harmonised standards as defined by the Regulation. As such, the direct regulatory benefits for consumers, environment, welfare of workers and the economy are linked to (i) the compliance of harmonised standards with EU legislation; and (ii) the effectiveness of the sector-specific legislation.

In the absence of sufficient data to quantify the benefits through market and non-market valuation approaches, the accompanying evaluation study used a survey with a scale of 1 to 5 scoring approach to estimate the benefits, resulting in the list of highest rated benefits from the ones shown below[169].

[168] These stated preference techniques use specially designed surveys to outline a hypothetical choice in a fictional market to gauge willingness to pay or accept. Companies were asked to value a series of percentage decreases in time of development and citation in the OJEU of standards in order to compute willingness to pay (WTP). The WTP represents the amount companies would be willing to pay to offset the costs generated by increases in time. Hence, we can assume that the opportunity costs are at least equal to the WTP.

[169] N=53, of which four Annex III organisations and 49 businesses.

Table 6: List of benefits of the Regulation rated by stakeholders.

Societal stakeholders	SMEs and large businesses
• Safety of consumers • Alignment with intended uses • The reliability of the system's operation and its quality assurance protocols • The influence on consumer behaviour due to attention given to the certification mark • Promotion of environmental sustainability • Impact on broader environmental policymaking	• Representation at the political level • Representation of sector-specific issues. • Contribution of industry expertise • Development & implementation of standards • Facilitation of cross-border Trade • Market penetration for innovations • Cost reduction for production • Increased product interoperability • Company growth and competitiveness • Competitiveness via conformity presumption • Competitiveness via common ICT standards

Source: Targeted industry and Annex III organisations surveys, see Annex V

Data for the perceived benefits for society were collected from the Annex III organisations targeted survey. The benefit analysis reveals that society gains significantly from the implementation of harmonised standards in the EU, notably through the alignment of products to their intended uses and their impact on broader environmental policymaking, as well as through improved. safety and the promotion of environmental sustainability. This is in line with results from a previous study[170].

For SMEs and large businesses, the benefit analysis highlights strong advantages in several areas, particularly sector-specific representation, industry expertise, and the development and implementation of standards. SMEs also benefit significantly from cost reduction, product interoperability, and enhanced competitiveness through conformity presumption and common ICT standards. These factors contribute to facilitating cross-border trade and market penetration for innovations, though representation at the political level and overall company growth scored lower, indicating potential areas for improvement in influence and expansion opportunities.

4.1.2.3. Cost-benefit analysis

The accompanying evaluation study offers an attempt for a cost-benefit analysis based on a number of assumptions and limitations.

The cost-benefit analysis does not directly compare compliance costs, since it is tied to the assumption that stakeholders are motivated by the advantages they gain from contributing to the consensus-building process behind harmonised standards. This process aims to align standards with broader societal goals rather than focusing purely on cost minimisation. However, the limitation of this assumption lies in its potential oversimplification. It does not consider the financial burden on organisations or public bodies and overlooks any potential trade-offs between the perceived benefits of participation and the actual costs involved. Additionally, it assumes that all participants value societal benefits equally, which may not always reflect the diverse priorities of stakeholders involved.

[170] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, 2021b, https://ec.europa.eu/docsroom/documents/50114

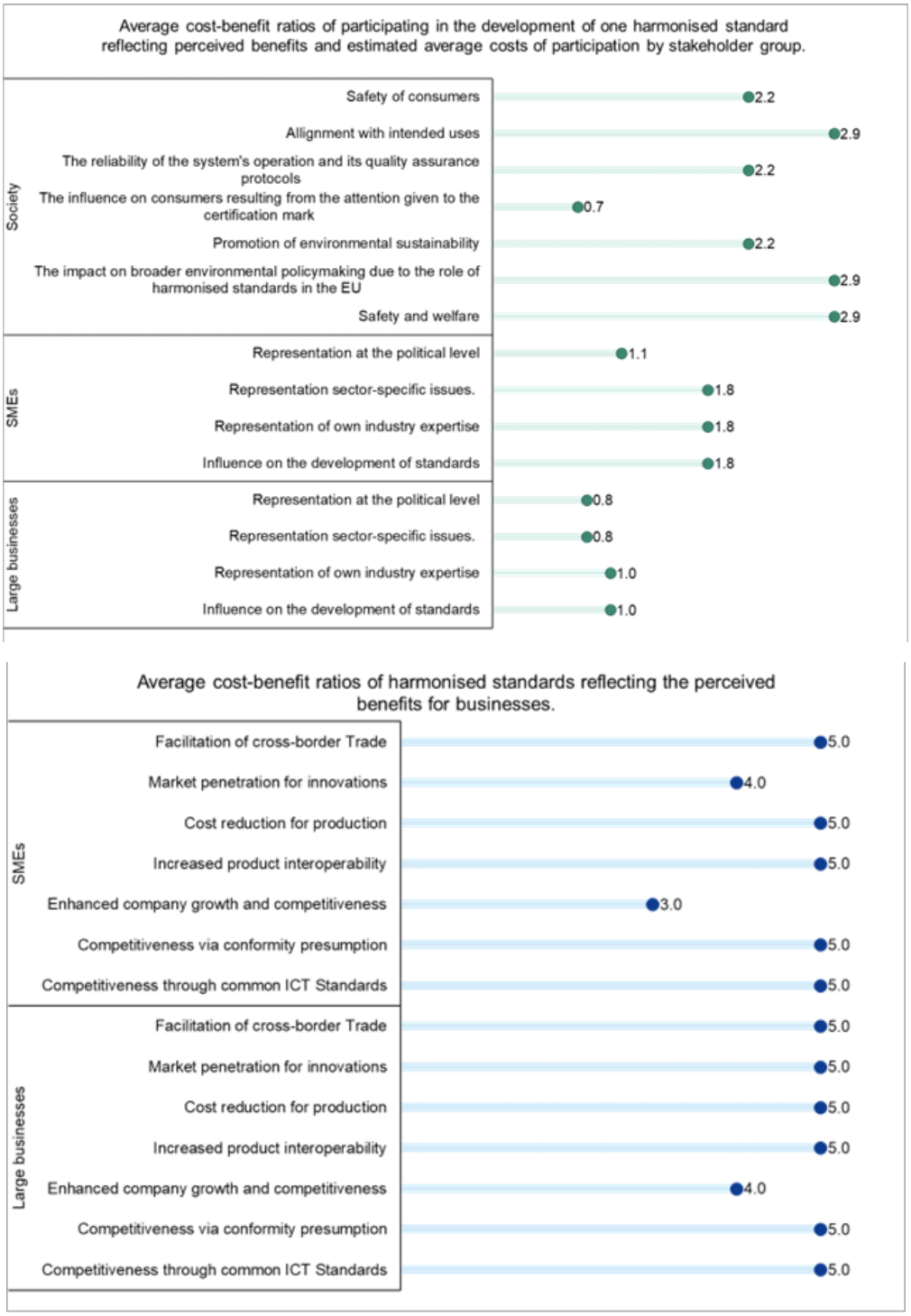
A cost-benefit analysis should in principle be based on monetary values. For costs, such data, with certain limitations, was gathered over the course of the study. However, as indicated in the previous paragraphs, due to the lack of sufficient monetary data, the study estimated the benefits on the basis of qualitative contributions in the targeted surveys with scores on a scale from 1 to 5.

In the attempt presented in the study, to compare costs and benefits on a consistent scale, the reported costs were standardised and cost-benefit ratios were calculated. The ratio sought to provide insight into the efficiency of the investment.

As a result, the ratio-based cost-benefit analysis presented by the study, although it shows a general proportionality of costs to benefits, does not allow to draw conclusions in a robust way.

It revealed a mixed picture, with positive outcomes for SMEs and certain areas of societal impact but limited perceived value in some respects, such as the influence of certification on consumer behaviour or business representation at the political level (see Figure 5 below).

Figure 5: Average cost-benefit ratios of participating in standard-development by stakeholder group



Source: Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.2.3, Figure 4-23

However, the analysis of stakeholder contributions to the consultation activities allows to conclude in a qualitative way that benefits outweigh the costs for the society as well as for businesses. This has been clearly confirmed by participants of the validation workshop carried out within the study.

4.1.2.4. Simplification and burden reduction

The 2011 Commission proposal for the Regulation[171] had as objective to set up an effective and efficient standardisation system, which provides a flexible and transparent platform for consensus building between all participants (recital 6 of the Commission proposal). The stakeholder-driven approach of the system was deemed as the right set-up to ensure an innovation-friendly system that is geared towards market and societal needs (recital 8, Commission proposal), and hence makes standards easily deployable. As such, the idea was to leverage the existing privately-run European standardisation system with minimum administrative burden for all stakeholders and the European institutions.

With this in mind, the Commission proposal foresaw a lean and simple procedure whereby the Commission was to issue standardisation requests to the European standardisation organisations, which would inform the Commission about whether they accept the request and about their activities undertaken to fulfil that request (Article 7 of the Commission proposal). As a safeguard regarding adherence of harmonised standards to EU legislation, the system of formal objections (as explained above) would be introduced whereby EU Member States or the European Parliament were to inform the Commission when "a harmonised standards does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union legislation" (Article 8(1) of the Commission proposal).

In the inter-institutional adoption process, the route of formal objections was deemed insufficient in terms of safeguards and the adopted Regulation today foresees a new role of the European Commission in terms of oversight and control of the process. The co-legislators added the provisions of Articles 10(5) and 10(6), through which the Commission was attributed new roles: first, together with the European standardisation organisations, the Commission is tasked to assess the compliance of draft standards with initial requests; and second, it is the Commission's responsibility to decide whether a harmonised standard satisfies the requirements in terms of compliance with Union legislation and to decide whether to publish their reference in the Official Journal of the EU or not.

This new role and responsibility for the European Commission, introduced through Regulation (EU) 1025/2012, had administrative consequences and became repeatedly subject to jurisprudence of the European Court of Justice (see Annex IX for an overview of relevant jurisprudence on European standardisation). In the James Elliott judgement[172] of 2016, the ECJ emphasised the Commission's role in initiating, managing and monitoring the standards-development process, and that the harmonising effect of standards is conditional on the Commission's decision to publish their reference in the Official Journal of the EU. The essential role of the Commission in the process was repeatedly mentioned by the ECJ, last in the ECJ ruling on 'access to standards' of 5 March 2024[173]. There, the Court emphasised the "central role" of the Commission in the European standardisation system and drawing up harmonised standards in the sense of Regulation (EU) 1025/2012.

[171] COM(2011) 0315 final and COD 2011/0150, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011PC0315
[172] Judgment of 27 October 2016, James Elliott Construction Limited v Irish Asphalt Limited C-613/14, paragraph 43.
[173] Judgment of 5 March 2024, Public.Resource.Org et Right to Know v Commission C-588/21 P.

In terms of administrative process, the Commission introduced in 2015 the requirement to accompany the draft standards offered for referencing in OJEU with an Annex that would allow to clearly identify the legally relevant parts of the draft standard offered for refencing (so-called Annex Z)[174]. In addition, since the early 1990s, the Commission has financed a system of so-called 'new approach consultants' within the European standardisation organisations, who were supposed to assist the technical committees in drafting legally sound standards. After the European standardisation system encountered a significant backlog between 2015 and 2017, when the Commission did not publish more than 2100 references to harmonised standards due to significant legal shortfalls of standards proposed for referencing, the new system of HAS consultants was established. The HAS consultants, in comparison to the previous system of consultants, are no longer anchored within the European standardisation organisations and are managed by an independent contractor following a public procurement open call. Their task is to do compliance assessment of draft standards submitted to the Commission, as described in section 3.1.1.

In terms of adoption procedure, following the James Elliot case, in 2018 the Commission changed the procedure to publish the reference of harmonised standards in the Official Journal of the EU. Whereas until then, standards' references 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 following a Commission Implementing Decision – a legally binding act – in the sense of Article 291 of the EU Treaty.

Therefore, while the Regulation did contribute to simplification in terms of overall alignment of national and European standards, the legal and procedural developments described above influenced the overall functioning of the European standardisation system and added more administrative burden both within the technical committees of the European standardisation organisations and on the European Commission (see further information in Annex IV). In light of the existing jurisprudence and the limitations of the current system, this burden on Commission and ESOs cannot be easily alleviated.

Nevertheless, in terms of remaining simplification opportunities, stakeholder consultations and desk research underpinning this evaluation revealed the following. First, there are opportunities to simplify and accelerate different parts of the standard-development process. This includes the preparation of standardisation requests (which often involves lengthy, unstructured exchanges between the Commission and ESOs) and the process for formal objections (where there is an opportunity to reduce the time needed to finalise a formal objection). Second, reporting mechanisms for ESOs and Annex III organisations could be simplified through more digitised online reporting processes, making the collected data more easily comparable. Third, more streamlined tracking of the lifecycle of harmonised standards can reduce the burden on the Commission and ESOs linked to monitoring standard-development. This would avoid the need to match data from different database when monitoring how standardisation requests are handled.

More broadly, a faster delivery of harmonised standards can also result in administrative simplification for businesses, as it provides legal certainty and cost savings through the presumption of conformity. When companies wait for the development and publication of

[174] SWD(2015) 205 final, Vademecum on European standardisation

harmonised standards, they may face costs, including those of using notified bodies for third-party conformity assessments or waiting to place their products. The evaluation study estimated that a company could save on average around EUR 3 700 used for conformity assessment for each harmonised standard available in time[175]. In addition, a faster and less complex standard-development process could reduce the time needed for experts to participate and thereby lead to a reduction of indirect compliance costs.

However, the rigidity in the standard-development process outlined by the Regulation and its reliance on the standardisation capabilities of the three European standardisation organisations limit opportunities for simplification and acceleration. More flexibility may be needed to simplify standardisation processes, while still ensuring full respect of jurisprudence with regard to the role of standards in the EU acquis.

The identification of common ICT technical specifications allows a simplification of public procurement processes, which can directly reference the specifications instead of needing to list all the technical characteristics, yet comprehensive data on its impact is missing.

4.1.2.5. Conclusions on efficiency

The evaluation of the efficiency of the Regulation faced significant data collection challenges, which prevent us from making definitive robust conclusions, in particular concerning the cost-benefit analysis.

There are some indications that the Regulation has been cost-effective to all affected stakeholder groups. Evidence presented by the accompanying evaluation study suggests that both large companies and SMEs recognise the benefits brought by the presumption of conformity linked to harmonised standards, and they still use harmonised standards and participate in their development, even if this bears costs (such costs though remain relatively high for SMEs). Although the costs for societal stakeholders are higher than for industry stakeholders, the overall benefits for society (consumers and workers' safety, environmental protection, etc.) are still perceived to be high. Also, a large part of the costs for Annex III organisations in standardisation activities, falling within the scope of the Regulation, is offset by EU financing.

Some areas for improvement were detected in the cost-effectiveness of the Regulation over time. Direct compliance costs, including administrative burdens, are slightly increasing for the European Commission, ESOs, NSBs, and Annex III organisations. Furthermore, all businesses face growing opportunity costs from the increased time needed for developing harmonised standards in compliance with EU law, and the delays stemming from checks and balances leading ultimately to their citation in the OJEU. Moreover, indirect compliance costs related to expert participation remain significant due to the long duration and complexity of standard-development processes. It was observed that harmonised standards do not appear to provide a competitive advantage in international trade, as costs for placing products in Canada, Japan, Korea, and South Africa are perceived to be lower than in the EU.

In terms of administrative burden, the legal and procedural developments described in Section 3 above (notably the Commission's responsibility to assess the compliance of draft standards for

[175] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Annex IV, Section 6.6.1.

initial requests and to decide whether a harmonised standard satisfies the requirements and whether to publish their reference in the Official Journal of the EU or not, combined with subsequent jurisprudence) introduced significant administrative burden both within the technical committees of the European standardisation organisations and on the European Commission.

As such, while European harmonised standards remain by far more efficient than fragmented national standards, the Regulation added administrative burden to the overall system, which is nevertheless necessary to guarantee the overall legal effect of harmonised standards, as affirmed in the law and through jurisprudence.

In addition, as regards the financing of the ESOs, the Regulation set out to reduce administrative burden by adding the possibility of lump sums in supporting the European standardisation organisations. Overall, lump sums were of use for limited activities of ESOs between 2015 and 2020, but were largely deemed not useful for most financing activities.

4.1.3. Coherence

The assessment of the coherence of Regulation 1025/2012 on European standardisation analyses both internal and external coherence of the intervention, i.e. between its various internal elements and vis-à-vis other relevant EU legislative measures.

4.1.3.1. Internal coherence

The institutional setup of European standardisation before the entry into force of Regulation 1025/2012 was governed by three different legal acts, namely Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[176], Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation[177] and Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information technology and telecommunications[178].

The Regulation streamlined and brought together the already existing regulatory aspects of EU standardisation into one legal act, in line with its objectives.

The Regulation aims to balance the public and stakeholder interest, stakeholder participation and business interests. In this regard, certain trade-offs become evident in the analysis of the provisions on cooperation between the ESOs, NSBs, Member States and the Commission for the purposes of development of standardisation deliverables on one side, and provisions on stakeholder participation in the process, on the other side. As indicated in the effectiveness analysis (Section 4.1.1), there are also certain trade-offs between the objective of accelerating standard-development processes and increasing inclusiveness.

The accompanying evaluation study analysed responses to the public consultation and interviews and concluded a consistency of the views of industry and societal representatives that praised the

[176] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204, 21.7.1998, p. 37–48

[177] Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation, OJ L 315, 15.11.2006, p. 9–12

[178] 87/95/EEC: Council Decision of 22 December 1986 on standardization in the field of information technology and telecommunications, OJ L 36, 7.2.1987, p. 31–37

Regulation for streamlining the legal framework and increasing inclusiveness compared to how the situation was before its entry into force[179]. The Regulation's integrity and governance is considered by the respondents in the surveys as preserved during the standards development process and within the ESOs, in line with EU interests and values.

Over the last decade, the annual work programmes of the ESOs show alignment with the policy objectives and approach to European standardisation, as set out in policy documents like the Commission Communications[180].

Certain challenges were found in the implementation; however, these do not relate to inherent conflicts or contradictions among the different provisions and activities of the Regulation. This indicates that although the regulatory provisions were well-founded, and compliance efforts were made in good faith, the obstacles to achieving full effectiveness related more to practical or operational difficulties rather than to issues with the Regulation itself.

4.1.3.2. External coherence

The external coherence of the Regulation is assessed from the perspective of its contribution to the implementation of the NLF, its link to wider EU policies and priorities and its implementation at national level.

With standards being used to demonstrate conformity with essential requirements, the Regulation plays a central role in the effective functioning of the NLF. The 2022 evaluation study of the NLF highlights that its continued effectiveness remains contingent on the prompt delivery of European standards[181]. The continued importance of harmonised standards for the implementation of the NLF was also confirmed by industry stakeholders consulted in interviews or the call for evidence underpinning the evaluation study. Industry organisations underlined that the Regulation and the presumption of conformity brought by harmonised standards brought undisputable value to the NLF.

The legislative acquis building upon or referring to harmonised standards has expanded (see Section 3.2.1) in the last decade. However, as described in Section 3.1.1 above, the co-legislators have started to include in a range of product legislation a possibility to adopt common specifications via implementing acts as a fallback option to harmonised standards, in order to pre-empt situations, in which harmonised standards are lacking, are not delivered within the deadline or do not comply with the standardisation request[182]. The latest ecodesign regulations[183] foresee the possible use of "transitional methods" in the absence of relevant standards and until the publication of the references of the relevant harmonised standards in the Official Journal of the EU. In certain cases, the co-legislators' agreement on the European Health Data Space (EHDS) even foresees common specifications adopted by the Commission as a primary means to implement the essential requirements[184]. This is an important trend that suggests a need for

[179] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.3
[180] See COM(2011) 311, COM(2018) 764, COM(2022) 31
[181] European Commission, Commission Staff Working Document – Evaluation of the New Legislative Framework, 2022.
[182] Proposed to be expanded across a wider range of product legislation as part of the Commission's fourth simplification omnibus package, presented on 21 May 2025.
[183] For instance, Commission Regulation (EU) 2023/1670 of 16 June 2023 laying down ecodesign requirements for smartphones, mobile phones other than smartphones, cordless phones and slate tablets
[184] Proposal for a Regulation on the European Health Data Space, final compromise text, 18 March 2024, 7553/24

alternative options and, in some cases, lack of trust in the timeliness and appropriateness of harmonised standards.

Impact assessments of recent proposals[185] also argue that harmonised standards often need to be supplemented by technical or common specifications offering a faster, more flexible, and comprehensive approach to address safety and environmental concerns, ensuring consistent application of legal requirements and a level playing field for manufacturers across the EU. Common specifications are also freely and fully accessible in the Official Journal of the EU.

Some stakeholders expressed concerns about the use of technical or common specifications potentially reducing the reliance on harmonised standards[186]. For these stakeholders, the use of such specifications should be a last resort in case it is not possible to develop a harmonised standard in a reasonable amount of time. For now, there has been no precedent for the fallback option to be used and for technical specification developed by the Commission to provide for presumption of conformity, hence its impact cannot be evaluated.

In addition, there is an increasing number of cases, in which legislation relies on standards outside the framework of the Regulation. Notably, the Corporate Sustainability Reporting Directive (CSRD) tasked the European Financial Reporting Advisory Group (EFRAG), a new standards-development body, to develop mandatory sustainability reporting standards[187]. In this regard, the Fit for Future Platform (F4F) recently flagged in its opinion on the Regulation the risk of fragmentation of standardisation efforts, with companies having to report both against EFRAG standards and conformity against harmonised standards[188]. On the other hand, this issue has not been highlighted by companies as a significant issue amongst the submissions that have been made to the Commission regarding the perceived burden of the new sustainability reporting requirements under the CSRD.

The evaluation study shows that the General Product Safety Regulation (GPSR, Regulation (EU) 2023/988) further highlighted some incoherences in the terminology and application of harmonised standards with the text of the Regulation[189]. The definition of harmonised standards in the Regulation is not consistent with the terminology that is presented in the GPSR when it comes to standards. This has resulted in incoherences between the procedures when standards are requested under the GPSR, and those procedures that are established through Article 10 of the Regulation.

Finally, about the application at national level, evidence shows that no issue related to coherence was detected in collaboration and transparency among ESOs and NSBs/NCs/NSOs. However, it was found that the conditions for societal stakeholders (Annex III organisations) to participate in the European standardisation system at the national level are still fragmented, preventing full inclusiveness. The same applies to difficulties in joining international standards-development

[185] Impact assessments for the Machinery Products Regulation (SWD(2021) 82 final), Construction Products Regulation (SWD(2022) 88 final), Toy Safety Regulation (SWD(2023) 269 final) and the AI Act (SWD(2021) 84 final)

[186] See synopsis report in Annex V, as well as the Fit for Future Platform opinion 2023/4, The functioning of European standardisation regulation, https://commission.europa.eu/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof/fit-future-platform-f4f-2021-2024/adopted-opinions_

[187] Directive (EU) 2022/2464, Article 29b

[188] Fit for Future Platform Opinion 2023/4, The functioning of European standardisation regulation, https://commission.europa.eu/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof/fit-future-platform-f4f-2021-2024/adopted-opinions_en

[189] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.3.1.1

work. Consequently, the inclusiveness of societal stakeholders at the national level varies across Member States. Also, the costs of participation tend to differ across Member States, further affecting their participation in the work of the NSBs/NCs/NSOs[190,191].

4.1.3.3. Conclusions on coherence

The Regulation is internally coherent and balanced in terms of the public and stakeholder interest, stakeholder participation and business interests, although certain trade-offs between speed and inclusiveness in standard-development are apparent. Challenges identified in the effectiveness analysis are not related to incoherences among provisions and activities within the Regulation but are more related to their factual implementation. The Regulation has also been fundamental for the implementation of the NLF.

However, four relevant developments have emerged with regards to the external coherence of the Regulation:

- An increasing number of sectoral legislations include the fall-back option of common specifications through implementing acts, showing that the co-legislators saw a need for alternative routes when harmonised standards are not available (in a timely manner);
- Outside the NLF, there is a fragmentation of standardisation efforts with a trend for reliance on alternative means and standards-setting bodies besides the ESOs for the delivery of common/technical specifications;
- The General Product Safety Regulation (GPSR, Regulation (EU) 2023/988) led to some incoherence in the terminology and application of harmonised standards;
- The conditions of participation in the European standardisation system for societal stakeholders are still fragmented at the national level.

4.2. How did the EU intervention make a difference and to whom? (EU added value)

The evaluation study shows that the added value of European standards lies in its contribution to increased EU trade, increased market value, increased influence on international standardisation and improved inclusiveness (compared to national systems)[192].

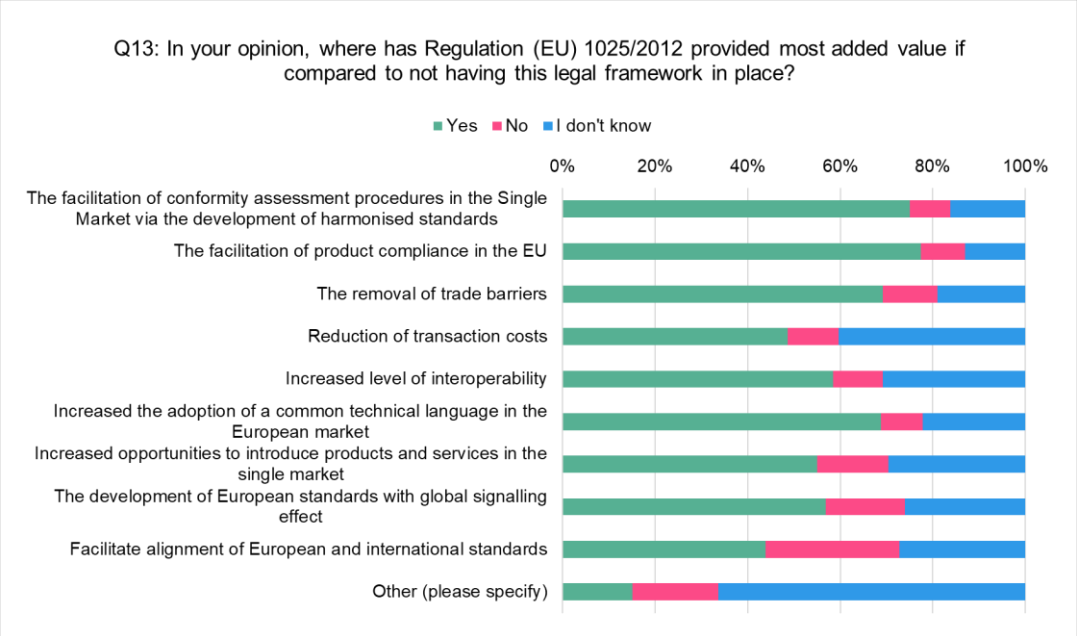
European standards facilitate trade by eliminating technical barriers from differing national standards. They generate market value by reducing production and compliance costs. They provide a moderate effect on EU influence on international standardisation and formalise the inclusion of societal interests in standardisation through Annex III organisations.

In terms of EU trade, consultations[193] show that harmonised standards have enabled companies to rely on a single standard to produce goods and services across the EU, facilitating product compliance (see Figure 6 below). They have also built trust between companies and customers

[190] Annalisa Volpato & Mariolina Eliantonio (26 Mar 2024): The participation of civil society in ETSI from the perspective of throughput legitimacy, Innovation: The European Journal of Social Science Research
[191] ANEC/BEUC, ANEC and BEUC recommendations to adapt Regulation (EU) 1025/2012, 2024.
[192] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.4
[193] Respondents to the public consultation agreed that the Regulation facilitates conformity assessment (75%, n = 191), believe that it supports product compliance (78%, n = 197), and that it helps remove trade barriers (69%, n = 176). Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.4.1

and created lower technical trade barriers[194]. The value of products covered by harmonised standards represents a significant share of the EU economy, estimated in 2011 at over EUR 2.4 trillion per year[195]. The use of harmonised standards and their presumption of conformity in a range of product categories allow businesses to demonstrate conformity with essential requirements and apply the CE marking in a cost-effective manner across the entire Single Market.[196]

Figure 6: Public consultation responses on the EU added value by Regulation (EU) 1025/2012



Source: Public consultation underpinning the evaluation study, see synopsis report in Annex V.

As standards have become increasingly important for the effective implementation of the Single Market, EU's competitiveness, technological sovereignty and its success in the green and digital transitions (see Section 3 above), a strong added value for an effective EU Standardisation Regulation remains.

4.3. Is the intervention still relevant?

The evaluation aims to verify whether the Regulation and its objectives, as listed in Section 2, are still relevant in light of the current policy framework, including the green and digital transition and other challenges presented in the 2022 Standardisation Strategy (as detailed in the introduction), as well as the evolving standardisation needs as detailed Section 3.2 and the latest jurisprudence as described in Annex IX. The evaluation study concluded that most of the current objectives of the Regulation remain broadly relevant, yet they do not entirely reflect the new strategic priorities as detailed in the 2022 Standardisation Strategy and some of them are no longer relevant in the context in which the Standardisation Regulation operates. In this respect, the study identified a range of challenges to the relevance of the Regulation.

[194] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, 2021b, https://ec.europa.eu/docsroom/documents/50114

[195] European Commission, Executive Summary of the Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products, 2017.

[196] Ballor G. CE Marking, Business, and European Market Integration. Business History Review. 2022;96(1):77-108.

4.3.1. Speeding up standardisation

As detailed in section 4.1.1, even though time taken for standards-development has decreased, stakeholders still consider it not fast enough for today's rapid technological changes and legislative needs. Both the Commission – to meet legislative deadlines – and industry stakeholders – who rely on the presumption of conformity for market access – have high expectations for more rapid development of European and harmonised standards. This is particularly relevant in case of standards related to technologies with fast lifecycles. Moreover, as reported under the coherence section 4.1.3.2, several new legislative acts include the fall-back option of common specifications adopted as implementing acts, for the case that the standardisation process gets delayed or if delivered standards do not comply with legislative requirements. This shows that generally the European legislators acknowledge the need to have alternative options to the European standardisation organisations as the only choice for standards-development, especially if regulatory deadlines are at stake. The gap between rapid legislative changes and the standardisation system's slower pace is likely to widen. Therefore, the accompanying evaluation study found that the Regulation's objective of a general goal of "speeding up" standards-development is no longer sufficient, and that there is a need to address the specific objective of timely availability of high-quality standards to comply with legislative deadlines but also serving industry and social needs to comply with EU legislation[197]. It underlines that the Regulation currently does not allow for adaptability and flexibility of the standardisation development process to achieve this goal. It also does not allow the Commission to hold the ESOs to shorter, pre-specified delivery deadlines.

4.3.2. Delivering standards for the green and digital transition of the European economy

The public consultation shows that stakeholders perceive that the system established by the Regulation should improve its presence in many new policy and technology areas, in particular artificial intelligence, digital health and renewable energy technologies (50% or more of respondents) but also internet of things (IoT), autonomous vehicles and space technologies (between 40% and 50% of respondents)[198]. Stakeholders expect the speed of standards-development time to decrease for digital standards, critical and emerging technologies including for the green economy, which have been recently regulated at the EU level (for instance on AI, cybersecurity, eco-design and net-zero industries). In addition, the need for speedy development of standards related to the green and digital transformation of the economy was highlighted by the High-Level Forum on European Standardisation set up by the European Commission, whose recent reports call for standards in the fields of critical raw materials, data interoperability, wind power or low-carbon cement[199].

At the same time, the evaluation found that the Regulation struggles to deliver on standards to support the legislative priorities linked to the European Green Deal and Europe's Digital Decade, partially but not entirely due to the above point on speed[200]. Consultations show that the factors that most worry consulted stakeholders in the field of emerging technologies for the digital and

[197] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.5.1.1
[198] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.5.2.1
[199] Reports to be found on the homepage of the High-Level Forum, European Commission, *High-Level Forum on European Standardisation*, https://single-market-economy.ec.europa.eu/single-market/european-standards/standardisation-policy/high-level-forum-european-standardisation_en
[200] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Sections 3.1.1 and 4.1.1

green transitions are the time taken to develop and adopt European standards (43% of respondents to the public consultation), the lack of experts and financial resources to run new technical committees (46% and 43%, respectively, of respondents to the public consultation), and the primacy of international standards (32% of respondents to the public consultation).

Additionally, the study identified some concerns regarding the adequate representation of public interest in the field of emerging technologies. Studies have questioned the adequacy of the system established by the Regulation for AI issues. The particular concern is related to the significant role played by the ESOs, in an area that has implications for fairness, privacy, transparency and other ethical considerations[201]. This links to the increasing trend that nowadays, standards do not only address product safety but broader issues. This seems to pose a challenge to the current set-up, linking back to its capacity to attract new technical expertise and knowledge into the standards-development process.

This finding is consistent with opinions from consumer rights organisations and trade unions. They emphasise the necessity of improved stakeholder participation to ensure proper representation of the public interest[202]. This is the case of standardisation of emerging technologies, such as AI and Big Data, due to implications for consumer protection and fundamental rights, requiring unambiguous EU legislation[203]. They argue that relevant stakeholders must be actively engaged in the development of the standards.

The evaluation finds a trend that alternative routes for standards-development not only can be found in EU legislation, as assessed under coherence (Section 4.1.3), but also outside of EU harmonisation legislation. European industry stakeholders rely increasingly on fora and consortia for technical specifications in areas like automotive data[204], 5G/6G[205] or electricity grids[206]. Many of these technical specifications are available in digital and open-source format.

4.3.3. Anticipating standardisation needs

The study found that the capabilities of the current legal framework to anticipate standardisation needs are hampered by: (i) perceived difficulties in delivering on important topics like hydrogen infrastructure, low-carbon cement, cybersecurity, quantum technology and data exchange as detailed in the previous point; and (ii) ineffective involvement of researchers and linkages to pre-normative activities in the standards-development process.

Section 3.1 revealed that, despite the allocation of specific funding via action grants to the ESOs, which typically fund pre-standardisation activities (roadmaps, mapping exercises) and the set-up of organisational structures (like coordination groups), many priority requests from the Annual Union Work Programme on European Standardisation related to the green and digital transition in 2022 and 2023 experienced substantial delays or received no response. Such issues become

[201] Gamito, Marta Canteiro, The Role of ETSI in the EU's regulation and governance of artificial intelligence. In Innovation: The European Journal of Social Science Research , 2023.
[202] ANEC/BEUC, ANEC and BEUC recommendations to adapt Regulation (EU) 1025/2012, 2024. ETUC, ETUC feedback on the evaluation of the Regulation 1025/2012 on European standardisation, 2023.
[203] ANEC/BEUC, ANEC and BEUC recommendations to adapt Regulation (EU) 1025/2012, 2024. ETUC, ETUC feedback on the evaluation of the Regulation 1025/2012 on European standardisation, 2023.
[204] See for example https://catena-x.net/en/1/vision.
[205] See for example 3GPP, https://www.3gpp.org/
[206] First technical specification for public procurement purposes will be developed by ENTSO-e, https://www.entsoe.eu/.

even more relevant when considering that these topics are related to areas where stakeholders expect improved presence as listed under the previous point.

This shows that the current stakeholder-driven approach of the European standardisation system is not sufficient to anticipate standardisation needs especially in areas where new industrial value chains are in the process of being established, despite deploying tools provided for by the Regulation (Action Grants, AUWP), additional tools (such as the Rolling plan on ICT standardisation) and complementary efforts to convene stakeholders (industrial alliances, High-Level Forum on European standardisation, Multi-Stakeholder Platform on ICT standardisation). Additional efforts are needed to raise awareness and improve engagement of relevant stakeholders, including researchers and research-performing organisations. Tools such as the Horizon Standardisation Booster (HSBooster)[207] and the Code of practice on Standardisation in the European Research area[208] can help in more effective involvement of researchers in pre-normative research activities and standards development.

4.3.4. Standards to be referenced from outside the European standardisation system for public procurement (or other purposes)

Section 4.1.1 found that process of identifying and broadening the use of common ICT technical specifications in public procurement (Article 13 and 14 of the Regulation) has delivered only until it was stopped in 2017. However, the study finds that considering that the overall ICT landscape is rapidly evolving, including outside the work of the ESOs, this objective of the Regulation remains relevant for public procurers looking for interoperable and legally compliant technical specifications from other sources, in case there may not be suitable EN or hEN standards available on time[209]. In addition, ICT technical specifications from SDOs, fora and consortia other than those formally recognised in the Regulation can provide for interoperability of trans-European digital public services, in accordance with the Interoperable Europe Act.

Therefore, a process according to which it can be examined which technical specifications from beyond the three ESOs complies with EU legal requirements, while at the same time respecting the same principles of openness, consensus and transparency is still relevant. In fact, this could be relevant not only to the ICT field but any other field in emerging or green technologies where other organisations are producing standards faster and are readily available when the EU legislator needs them. The need for the Commission for a process according to which it could assess standards against the above criteria and then recommend it to public procurement or other purposes still proves relevant.

4.3.5. Standards to be used in the social area

The evaluation study found that the use of standards in the social area should be considered with caution. Societal stakeholders raised the concern that social and ethical aspects of European legislation should remain at the political level without being discussed in the technical realm of standardisation. According to ETUC, ANEC and BEUC there is a real risk that in sensitive areas - like data privacy, AI trustworthiness, fundamental rights, IT infrastructure security, e-health, and web accessibility – the legislation or the standardisation requests of the Commission remain

[207] High-level Recommendations for the Future Standardisation Booster Framework Contract, https://zenodo.org/records/14534475
[208] Commission Recommendation (EU) 2023/498 of 1 March 2023 on a Code of Practice on standardisation in the European Research Area, C/2023/1320
[209] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.5.1.2

too vague, leaving space for misinterpretations. A study by the Corporate Europe Observatory suggests that harmonised European standards are not objective and neutral enough to develop details on fundamental rights, given the high influence of corporate actors. [210]

Consumer rights organisations and trade unions argue that relevant stakeholders must be actively engaged in the development of the harmonised standards[211]. In addition, they consider the involvement of technical experts who are representing industry to be insufficient to safeguard the public interest[212].

4.3.6. Latest jurisprudence, including on access to standards

In November 2024, the Commission hosted an expert workshop (see Annex VII) with recognised scholars and academics in the legal, political science and economics fields to gather their views on how fit for purpose the current legal framework on European standards (Regulation (EU) No. 1025/2012) is. Most scholars mentioned that ECJ jurisprudence over the last decade, namely the judgements on James Elliott (2016)[213] and Public.Resource.Org (2024)[214] (see Annex IX) posed a challenge to the implementation of the Regulation. The workshop demonstrated a wide agreement among academics that there is a need to look at creating legal certainty on the status of harmonised standards in the EU acquis, on the roles and responsibilities of stakeholders and the Commission, and to provide a precise description of the legislative procedures relating to harmonised standards. In terms of transparency and access to standards, scholars agreed that the provisions of the Regulation shall be looked at to take account of latest jurisprudence. Strong views exist in favour of full publication of harmonised standards in the Official Journal of the EU, taking account of the ECJ affirming that harmonised standards are part of EU law and that transparency and accessibility principles apply as part of the rule of law.

The evolving role of standards, moving from product safety requirement to affecting broader societal aspects, was raised as a strong argument to support a revision of the Regulation. This trend could already be witnessed in recent harmonised standards work tasked on artificial intelligence but also toys or clean technologies, where it would be of utmost importance to demonstrate the legitimacy of standards and compliance with the EU rules and values.

4.3.7. Promotion of EU interests and values in international standardisation

While interviews with industry stakeholders and experts in different sectors confirm that the Regulation is still relevant to allow the ESS to promote EU values and interests in the international context, concerns of industry suggest that a certain lack of coordination between main actors of the ESS at European and national level, including Member States and national standardisation bodies who have voting rights in ISO, IEC or ITU, has a negative impact on the EU's capacity to influence the discussions and consensus building[215]. This is to be considered against the backdrop of geopolitical challenges described in section 3.2.2 and a main concern of industry that non-EU countries, in particular China, are increasingly taking over leading roles in

[210] Bias baked in - How Big Tech sets its own AI standards, Corporate Europe Observatory, 2025 https://corporateeurope.org/en/2025/01/bias-baked

[211] ANEC/BEUC, ANEC and BEUC recommendations to adapt Regulation (EU) 1025/2012, 2024. ETUC, ETUC feedback on the evaluation of the Regulation 1025/2012 on European standardisation, 2023.

[212] ETUC, ETUC feedback on the evaluation of the Regulation 1025/2012 on European standardisation, 2023; ECOS, Input EC Call for evidence, 2023.

[213] Case C-613/14, EU:C:2016:821

[214] Case T-185/19, EU:T:2021:445

[215] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.5.2.4

strategic committees and working groups at the international standardisation bodies and increasing its overall participation[216].

Interviews also confirmed that fragmentation between the EU and the international level could be a major risk with technologies that already rely on standards developed outside ESOs, especially if EU actors have less leverage to influence them.

4.3.8. Inclusiveness

While the public consultation shows that there is consensus (61%) in all stakeholder groups regarding the relevance of the regulation in ensuring the integrity and inclusiveness of the ESS, several obstacles persist, as also reported in Section 3, and identified by the High-Level Forum on European standardisation in its peer-review of NSBs focusing on the level of inclusiveness at national level[217].

Data collected in the public consultation underpins the above finding. Stakeholders had mixed views on the suitability of the Regulation for addressing wider strategic objectives, notably regarding the development of urgent market needs[218], the development of service standards[219], the EU's role in global standards-setting [220], the promotion of EU democratic values globally[221] and the inclusion of cutting-edge research in standards-development.

Targeted survey showed that the timeliness of standards development for industry implementation was considered inadequate by 20% (disagree) and 18% (strongly disagree) of respondents, although 26% did agree the process was timely, while 30% were neutral.

4.3.9. Alternative routes

Harmonised European standards undergo a specific development process and confirmation steps by the Commission, prescribed in the Standardisation Regulation. As signalled in the coherence section, there is an increasing number of Single Market product legislation that includes the fallback option of technical specifications to be adopted by the European Commission in case harmonised standards are not available (and subject to other strictly defined conditions). For the moment this has been only a precautionary measure and there is no precedent for a technical specification developed by the Commission to provide for presumption of conformity, hence its impact cannot be evaluated.

The coherence section also mentions the case of the European Financial Reporting Advisory Group (EFRAG). EFRAG has existed since 2001 and in 2023 the EU assigned to it a new role via the Corporate Sustainability Reporting Directive, to draft European Sustainability Reporting

[216] For instance, China has had the largest share of chairmanships of ITU-T working groups (24.2%). In terms of ISO secretariats in technical committees and subcommittees, China's share of secretariats the proportion of China's increased from 5.0% to 9.4% between 2011 and 2022, see Rühlig T.N. (2023). The New geopolitics of technical standardisation: A European perspective. Future Europe, 3(1), 102–109, and Rühlig T.N. (2024). China's New Technical Standardisation Power: A Challenge for Europe. In: Freimuth, J., Kaiser, S., Schädler, M. (eds) Standardization Strategies in China and India. Professional Practice in Governance and Public Organizations. Springer, Wiesbaden. https://doi.org/10.1007/978-3-658-45583-5_28.

[217] Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.5.2.3

[218] For the development of urgent market needs, 28% of respondents believe the Regulation is suitable to a large extent, 26% to a moderate extent, 18% to a small extent, 10% not at all, and 18% does not know.

[219] For the development of service standards , 23% of respondents believe the Regulation is suitable to a large extent, 17% to a moderate extent, 14% to a small extent, 4% not at all, and 41% does not know.

[220] For EU's role in global standards-setting, 21% of respondents believe the Regulation is suitable to a large extent, 28% to a moderate extent, 19% to a small extent, 13% not at all, and 19% does not know.

[221] For the promotion of EU democratic values globally, 18% of respondents believe the Regulation is suitable to a large extent, 32% to a moderate extent, 13% to a small extent, 11% not at all, and 26% does not know.

Standards and/or draft amendments to these standards. Moreover, implementing or delegated acts are being used today to support EU legislation with technical details.

Referencing existing international standards from ISO, IEC and ITU-T, instead of developing new harmonised standards from scratch is also a common practice and is used in several legislative acts. In addition, in some cases, some actors have called for dedicated sectoral standards bodies (beyond the existing European standardisation organisations), as demonstrated by the European Parliament's proposal for a pilot project investigating the feasibility of a European body for jet fuel standards[222].

No analysis exists as to the root cause of these developments. It is clear however, that the above options vary in terms of timing, use of industry know-how, the adoption process, verification of alignment with EU legislation, inclusiveness, accessibility and control over who develops these standards. It appears that it was the choice of the legislator and co-legislators to choose which option to ask for when technical requirements needed to be developed to support EU legislation, possibly based on different sectorial considerations. The various problems of the current European standardisation identified in this evaluation could have logically contributed to this.

On the one hand, alternative routes can lead to more flexibility for the European legislators when it comes to developing technical requirements when they consider the development of harmonised European standards too lengthy, constraining or unable to meet sectoral needs.

On the other hand, the increasing use of alternative routes can lead to a possible fragmentation of the standardisation system with varying levels of quality control and stakeholder involvement.

4.3.10. Conclusions on relevance

While the Regulation's objectives remain broadly relevant, they do not fully reflect the new strategic priorities outlined in the 2022 Standardisation Strategy. In particular, the urgency of speeding up standards-development is underscored by the fast-paced technological advancements and legislative requirements related to the green and digital transitions. The relevance section highlights the importance of better anticipation of standardisation needs (also at the pre-normative stage), as well as more robust stakeholder participation and technical expertise to support emerging technologies, while emphasising caution with standardising broader societal issues. Furthermore, the section stresses the need to improve coordination among the European stakeholders active in international standardisation to ensure EU interests and values are promoted globally. The section also underlines that the European legislators may need alternative options to the ESOs, especially if regulatory deadlines are at stake.

5. CONCLUSIONS AND LESSONS LEARNED

5.1. Conclusions

This evaluation has assessed the performance and impact of Regulation (EU) No 1025/2012, which organises the interface between the Commission and the broader, privately-run European standardisation system with regard to the delivery of harmonised standards in support of EU law.

[222] Pilot project under the 2024 budget, https://www.europarl.europa.eu/doceo/document/BUDG-DT-759726_EN.pdf

As a measure of success, the evaluation assesses whether standards that were requested by the Commission in accordance with the Regulation are delivered in an effective, inclusive and timely manner.

In relation to the original objectives of the Regulation, the following improvements to the overall functioning of European standardisation were found: (i) the standards-setting process was made faster (from a baseline of more than nine years to six years currently); (ii) conflicting national standards were removed in favour of European standards; (iii) the European standardisation system became more inclusive of societal stakeholders and SMEs; (iv) a structured approach to ICT standardisation was established. However, considering today's needs and how the Regulation serves overall EU policy and legislative objectives, the system struggles to meet both policy and market needs.

The Regulation was moderately effective in increasing the speed of delivery of European standards and improving overall stakeholder participation. However, despite improvements, with an average standard-development process of six years (of which over three years for drafting and consensus building), the process is still much too slow. The different steps of the standard-development process, including negotiations on standardisation requests, the consensus-building and drafting process managed by the ESOs, and the required assessment and citation of the standards by the Commission are all too lengthy.

The evaluation shows that this duration does not meet policy and market needs. First of all, a harmonised standard is regularly available and cited in the OJEU only after the date of application established in the respective law. Second, while stakeholder views are mixed, a significant number of businesses has expressed dissatisfaction with the time needed to develop harmonised standards[223]. Third, some other international standard-setting processes are significantly faster (even compared only to the time taken for drafting and consensus-building for harmonised standards).

Drivers behind the long duration of the process include procedural hurdles, recurrent quality gaps, a lack of communication and resources in the European standardisation system and insufficient deployment of digital technologies. Furthermore, the legal status of harmonised standards as forming 'part of EU law' and the reinforced role of the Commission in initiating, managing and monitoring the standards-development process was emphasised in a series of CJEU rulings. Consequently, more safeguards and control mechanisms were put in place over time. Combined with significant quality issues in draft harmonised standards, this has led to delays and an increased administrative burden in the whole framework.

Moreover, with the Regulation only allowing standardisation requests to be addressed to the three ESOs, the Commission lacks alternatives if harmonised standards are not developed in a timely manner. ESOs (whose business models vary significantly) do have a general incentive to work on the development of harmonised standards given their intrinsic relevance and legal value. However, ESOs may need further incentives to adapt or accelerate their ways of working.

[223] According to the public consultation, 24% of businesses (N=58) and industry associations (N=63) consider that the Regulation has not achieved its objective of reducing the time taken by the standardisation process at all. According to the targeted survey, 52% of industry stakeholders (N=50) disagreed or strongly disagreed with the statement that the time to develop harmonised standards is efficient. See Annex V.

Introducing more flexibility into the system could encourage innovation, ultimately benefiting the standardisation process as a whole.

The slow speed is considered to hamper the positive effects of harmonised standards on the competitiveness of EU industries. In particular, the late availability of harmonised standards can generate legal uncertainty and additional costs for businesses. Furthermore, it reduces the EU's ability to influence international standardisation, which is crucial for the global competitiveness of EU businesses.

While stakeholder representation has improved under the Regulation, notably through the introduction of Annex III organisations, standardisation processes are still too complex, costly and time-consuming for SMEs and societal stakeholders to participate effectively. Annex III organisations do not always perceive their participation as leading to effective results or input as being taken into account sufficiently. Structural barriers for the effective representation and participation in standardisation of people with disabilities also persist. Drivers for this include the long duration of processes and the associated cost of participation and the governance models of ESOs and NSBs. While there is a certain trade-off between speed and inclusiveness, and standard-setting processes must foresee enough time for balanced stakeholder participation, more efficient processes can also reduce barriers to participation. Another driver is the lack of capacity and skills in standardisation among underrepresented organisations. It can be particularly challenging for small organisations to engage the skilled experts needed for effective participation.

In terms of efficiency, the evaluation faced significant data collection challenges, in particular concerning the cost-benefit analysis. In order to mitigate this lack of substantial data, the evaluation study adopted a mixed method approach, with information on industry costs collected through the public consultation, targeted surveys and interviews, and subsequent triangulation of the evidence to ensure the robustness of data. Whilst this is a sub-optimal approach given the lack of data provided, it suggests that the Regulation has been cost-effective for all affected stakeholder groups, as the overall direct and indirect benefits are higher than the costs incurred. Both large companies and SMEs can benefit from the presumption of conformity linked to harmonised standards, and some of them participate in the development of harmonised standards. Nevertheless, costs of participation (in light of the long duration and complexity of the standardisation process) are more problematic for innovative SMEs, startups, civil society and academia than for large companies, which may give a competitive advantage to larger incumbents in the standardisation process.

While this evaluation has highlighted some opportunities for simplification (notably related to reporting, monitoring and various procedural steps), the rigidity in the standard-development process outlined by the Regulation and its reliance on the standardisation capabilities of the three European standardisation organisations limit opportunities for simplification and acceleration.

As regards how relevant the Regulation is to respond to innovation, the evaluation found a lack of speed, a lack of responsiveness to the latest technology trends and a lack of anticipation of standardisation needs. Very few harmonised standards are updated every five years and almost half of harmonised standards in the OJEU are more than ten years old. This indicates that harmonised standards do not necessarily follow innovation cycles. External factors, such as

accelerated technology cycles in the digital and green fields, an ageing population of technical experts, geo-economic developments, the increased assertiveness of non-EU countries in international standardisation, and CJEU jurisprudence have made weaknesses in the current system more evident and pose challenges to the EU's role as a global standard-setter.

5.2. Lessons learned

The evaluation has identified several lessons learned that can inform future improvements to the legal framework for European standardisation, subject to a potential future impact assessment:

- **Speed and responsiveness to innovation are essential**: High-quality harmonised standards need to be developed and made available faster and more efficiently to meet policy and market needs. This requires streamlining procedures, improving transparency and communication between key players, tackling quality issues in an effective manner and better anticipating standardisation needs (even at the pre-normative stage, including with greater involvement of research). The use of digital tools can also help speed up the standardisation process and make it more efficient.
- **Balanced stakeholder participation is critical**: SMEs and societal stakeholders need to be able to participate effectively in standardisation processes. This requires making standardisation processes more accessible and inclusive, providing support to facilitate balanced participation and boosting awareness, skills and expertise among underrepresented stakeholders. While there is often considered to be a trade-off between speed and inclusiveness, more efficient, digitalised and streamlined standard -development processes can help reduce the cost of expert participation (indirect compliance costs) and thereby accelerate standardisation without compromising inclusiveness.
- **Data gaps can be filled through more effective monitoring arrangements**: A more robust framework is needed for collecting and analysing data on the impact and effectiveness of harmonised standards. The evaluation has revealed significant data gaps in the current framework, which prevent an in-depth analysis of the impact of harmonised standards on competitiveness. First, data on harmonised standards is currently fragmented across databases, which makes it impossible to track the entire lifecycle of a standard (from standardisation request to harmonisation). Second, the actual involvement of different stakeholder groups in standardisation is not monitored effectively (for instance data on the number of participants and meetings in technical committees and working groups). Involvement of public authorities of Member States in standardisation activities is not monitored either. Third, there is insufficient data on the real efforts and costs borne by different stakeholders in all phases of the standard-development process. Measures could be considered to fill these data gaps while avoiding any disproportionate reporting burden.
- **Alternative routes for standardisation need to be considered**: In the current framework, in certain cases, the Commission is faced with the unavailability or late availability of harmonised standards without having any alternatives to provide clarity and legal certainty to businesses. In response, the co-legislators have opted for different standards-development routes in some policy areas, either by empowering the European Commission and EU agencies to develop common specifications or relying on other international or non-formal standards-development organisations organisations, fora and consortia based on their specific

legislative or market needs. This reflects the need for more flexibility in the system, in particular with regard to accelerated procedures adapted to market needs. Coherence between such parallel pathways should be carefully considered.

- **Role and responsibilities of the Commission and ESOs should be clarified**: The evaluation has highlighted the need for clarity on the responsibilities of different parties. This includes the responsibilities of the ESOs (for instance with regard to delivery deadlines and quality requirements), as well as the role of the European Commission in the standardisation process in light of CJEU judgments. This also involves optimising the Commission's involvement in processes (from the assessment of draft harmonised standards to the citation process) and ensuring that the Commission has the necessary resources and expertise.
- **Measures are needed to retain and strengthen the EU's role as a global standard-setter**: The evaluation has highlighted the importance of preserving the global impact of EU standardisation, in particular in light of the increasingly assertive position of non-EU countries. Speed, responsiveness to innovation and active stakeholder participation within the EU framework will enable a stronger global impact. While there has always been an assumed advantage to the close links between the European standardisation organisations and international standards-development bodies like ISO, IEC and ITU, the EU's role as global standard-setter is being challenged. The evaluation found that harmonised standards had a positive effect across the single market but less so when it comes to opening international markets. The intertwined relationship between European and international standards-development bodies therefore needs to be further assessed.

ANNEX I: PROCEDURAL INFORMATION

- **Lead DG**: DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)
- **Agenda planning/Work programme reference**: PLAN/2022/968
- **Organisation and timing**:
  - Work started in January 2023.
  - An Inter-Service Steering Group (ISSG) chaired by DG for Internal Market, Industry, Entrepreneurship and SMEs was established to this purpose, involving representatives from the Secretariat-General, Legal Service, DG for Research and Innovation, DG for Budget, DG for Competition, DG for Communications Networks, Content and Technology, DG for Defence Industry and Space, DG for Economic and Financial Affairs, DG for Employment, Social Affairs and Inclusion, DG for Energy, DG for International Partnerships, DG for Structural Reform Support, DG for Taxation and Customs Union, DG for Trade and DG for Internal Market, Industry, Entrepreneurship and SMEs.
  - The ISSG met six times (28 February 2023, 06 December 2023, 24 January 2024, 25 July 2024, 28 November 2024 and 11 April 2025).
- **Use of external expertise:** An external consortium led by Intellera Consulting SpA with Fraunhofer ISI and Trinomics B.V. produced a supporting study.
- **Fit for Future Platform** (F4F): Table 7 below summarises the opinion of the F4F Platform and the Commission's response as to how these issues are considered in its work.
- **Consultation of the Regulatory Scrutiny Board** (RSB): The evaluation was selected for scrutiny by the RSB and the board was informally consulted in an upstream meeting on 19 February 2024. The draft evaluation SWD was submitted to the RSB on 11 December 2024. A formal consultation of the RSB took place on 15 January 2025 and the board issued a negative opinion pointing to areas for improvement. Table 8 presents the RSB suggestions and how they have been addressed in the improved version of the SWD.

Table 7: Comments from the Fit-for-Future (F4F) Platform's opinion on the functioning of the European standardisation regulation[224]

Comments from the F4F Opinion	Follow-up
Refrain from a full revision of Regulation 1025/2012: There are **certain inefficiencies and areas for improvement** of how the European Standardisation system works. The objective should be to ensure the measures are proportionate to the needs of all involved stakeholders. It is crucial to acknowledge that the **issues of governance** and **'bottlenecks' in publication of standards** are linked intrinsically together.	The evaluation findings cover the overall implementation and impacts of Regulation (EU) 1025/2012, looking at its effectiveness, efficiency, coherence, relevance and EU-added value. Certain inefficiencies and areas for improvement were identified in the evaluation. The evaluation has a distinct retrospective focus, while looking at how the Regulation works in the current policy and legislative

[224] https://commission.europa.eu/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof/fit-future-platform-f4f-2021-2024/adopted-opinions_en

Many issues can be traced not to how the Regulation functions but to the **juridification of standards**. In general, stable criteria should be identified which could allow for a common interpretation between all stakeholders.	framework. The evaluation assessed in detail how the ECJ jurisprudence and implementation of certain provisions of the Regulation had an impact on the overall functioning of the European standardisation system. Administrative aspects were carefully assessed in this respect, especially when taking account of the ECJ pronouncing harmonised standards as part of EU law and consequences for the way the Commission handles the process of developing and adopting references of standards for publication in the Official Journal of the EU.
Ensure consistency with Regulation 1025/2012 across legislation: **new legislation** such as the Corporate Sustainability Reporting Directive (CSRD) are creating **knock-on effects on standardisation efforts**. In the case of CSRD this creates mandatory sustainability reporting standards and has tasked EFRAG with their development. EFRAG is a body that specialises in financial reporting. Sustainability reporting follows **the double materiality principle**, which means that reporting concerns both the effect of climate/sustainability on a company's finances and the effect of a company's finances and activities on climate/sustainability. The two aspects fall within the remits of competence of different standard setting bodies.	In line with the platform's suggestions, the evaluation assessed the coherence of the Regulation, including with other EU harmonisation legislation, over the last years. This includes legislation falling under the New Legislative Framework (NLF) but also other relevant pieces of EU legislation. In this respect, also the Corporate Sustainability Reporting Directive was looked at. The evaluation deliberates on cases, in which sectorial legislation relies on standards outside of the framework of the Regulation, and also highlights the fact that in revisions of NLF-relevant legislation, the co-legislators decided to build in a fall-back routes for missing harmonised standards via the development of common specifications via implementing acts.
Maintain the market-based approach to Regulation 1025/2012: Considering the targeted amendment to Regulation 1025/2012 of 14 December 2022 which reformed the governance structure of the ESOs, affecting ETSI, the Platform can support such structural changes. Standardisation is based in principle on the **needs of the market** which are then used to **support the implementation of public policies** to safeguard the public interest and comply with regulatory requirements. A key area that will **need to balance the needs of the market with public interest** is for matters related to fundamental rights. These considerations could lead to recommendations of how best to include **fundamental rights** in law and	Regulation (EU) 1025/2012 has as objective to set-up a legal framework to allow for the delivery of standards in support of EU policies and legislation. Standards-development outside of the remit of EU harmonisation or policy objectives remains a private undertaking and hence remains fully stakeholder- and market-driven. Contrary to the Fit for Future platform report, the Regulation's aim is to first serve public interests and societal needs, and then to cater for an approach that is compliant with market needs (and not vice versa). The evaluation touches upon implementation challenges, which can partially be drawn back to a different understanding of the purpose of the Regulation.

standardisation, potentially even establishing common rules for what elements of legislation affecting fundamental rights can or should be standardized. Furthermore, it is important to recollect that in accordance with Recital 12 of the Regulation, standards are inappropriate to address the workplace dimension.	As regards the dimension of fundamental rights and standards-development, the evaluation picks up on the fact that standards today have to cater for more than just product safety criteria – namely also socio-economic elements – which requires a new approach to standards development. The evaluation also goes into more detail on what this means for delivering on standardisation needs for EU policies and legislation informing a green, digital and resilient Single Market. Current standardisation work on AI or toys are a testament of the new dimension relating to standards-development and the critical role of societal stakeholders in the whole process.
Establish a formal and independent role for stakeholders for coordination of standardisation activities: The Platform acknowledges the Commission efforts to introduce a more strategic perspective and coordination in standardisation through the establishment of the High-Level Forum on Standardisation. The activities and the internal process of the forum should be clearly defined so that the forum contributes in a meaningful manner in prioritising European standardisation efforts.	The Platform acknowledges enhanced coordination needs in anticipating and informing standardisation work in a stakeholder-conducive format. The evaluation assesses the capacity of the European standardisation system to serve standardisation needs in new technology areas, where industrial value chains are in the process of being developed. It also acknowledges implementation modalities, like the High-Level Forum on European standardisation, and how successful it was in anticipating standardisation work.
Follow a horizontal approach for the adoption of common specifications: The Commission should work **towards a horizontal approach** in terms of criteria and processes for the development of **common specifications** via implementing acts. For consideration, the text on common specifications from the recently published in the Official Journal of the EU Regulation (EU) 2023/1230 of the European Parliament and of the Council on Machinery (OJ L 165/1 of 29.6.2023) new **Regulation on Machinery** must be used as the horizontal approach for new pieces of legislation. Furthermore, the Commission should be **clear about its intention to apply** this approach in their future legislative proposals. By sticking to the approach of the Machinery Regulation the Commission must also reaffirm that common	While the common specifications are not regulated by the provisions of Regulation 1025/2012, the evaluation has looked overall at this aspect under the chapter of external coherence of the Regulation. It acknowledges the fact that there is an increasing number of sectorial legislations which relies on this fall-back option of common specifications through implementing acts for a situation, where harmonised standards are not available.

specifications are only to be used as **a fallback option** to harmonised European standards under strict conditions when no other alternatives are possible and to support market certainty and ensure public interest is served where harmonised standards are absent.	
Reinforce inclusiveness in standardisation at European, national, and international level: The Regulation currently asks national standardisation bodies (NSBs) **to facilitate the participation of SMEs** in standardisation without giving any obligations of means - thus creating inequalities between NSBs as some favour this participation more than others. Furthermore, access alone does not guarantee the public interest being taken into account. Having **"access" (that is, openness) is not the same as having "effective participation" (that is, inclusiveness).** Participation needs not only to be simply possible and passively supported, but **actively encouraged and effectively facilitated** in line with Regulation 1025/2012. Inclusiveness can be reinforced as well without enacting explicit changes to the Regulation.	One of the important focuses of the evaluation is the framework for stakeholder participation in the standards-development process, and in particular aspects related to its effectiveness. In line with the opinion of the F4F platform, the evaluation analyses the extent to which participation of stakeholders leads to effective results, as well as impacting factors (complexity, costs, time). A dedicated working group under the High-Level Forum on European standardisation assessed how SME access to national NSBs can be improved, with several problems already identified, including required membership fees in many national standardisation bodies/committees and the large amount of time needed to invest into standards-development.
Ensure more researcher participation in standardisation: The **relationship between research and standardisation must be strengthened** as best it can, European initiatives such as STAND4EU, HSBooster, or the Code of Practice on Standardisation for Researchers are all positive developments. However more needs to be done to make **standardisation attractive for researchers** to participate in. In its current form, Regulation 1025/2012 does not sufficiently highlight this necessary interdependence and its mutual benefits. For example, there should be obligations to facilitate participation in standardisation for research actors, or increased awareness at the national level subject to periodic peer reviews.	The role of research organisations and public agencies has been assessed in the evaluation and various implementation activities were looked at in detail in terms of effectiveness. Certain challenges have been identified, for example the lack of professional incentives for researchers and the recognition for their standardisation work.

Table 8: Comments from the first RSB opinion on the draft SWD

Shortcomings	Follow-up
(1) The scope of the evaluation is not sufficiently clear. It is not analysed how the underlying business models of the European standardisation organisations affect the development of harmonised standards.	The evaluation has been revised to clarify the scope and the interface between the Regulation and the broader European standardisation system. Details on the scope of the Regulation and the evaluation have been added to Section 1. The role of the Regulation within the privately-run European standardisation system has been described in the dedicated Section 2.1.2. This also includes information about the business models of the ESOs and NSBs, although it should be noted that the European Commission has no means to access granular data on the finances of these private standards-development organisations.
(2) The impact of the regulation on fostering the EU's competitiveness and stimulating growth as well as the reasons for the regulation not attaining some of its main specific objectives are not sufficiently analysed.	There is limited data on the broader impact of harmonised standards on competitiveness and growth. Nevertheless, literature research and stakeholder consultations have revealed certain positive impacts, as described in Section 4.1.1.5, including impacts on Gross Domestic Product, labour productivity and Gross Value Added (GVA). Furthermore, an analysis of evaluations of sectoral harmonised legislation (NLF) has been deepened to identify data on cost savings associated with the use of harmonised standards for conformity assurance. While only very limited data could be identified, relevant information about cost savings has been added to Sections 4.1.1.5 (effectiveness) and 4.1.2 (efficiency).
(3) The coherence and relevance of intervention, in particular taking into account the increasing use of alternative routes to standardisation, is not sufficiently assessed.	The section on coherence was modified with more elements on internal coherence in particular. An analysis of the use of alternative routes has been included in the dedicated section 4.3.9.

Points to improve	Follow-up
(1) In the light of the specific role of regulation 1025/2012 within the ESS, the scope of the evaluation and use of corresponding terms should be clarified. Based on the analysis of the business models of ESOs and the model of financing of harmonised standards (also in light of the Court's latest judgment), it needs to be assessed whether the existing set up provides the right incentives to the standardisation bodies and involved	The terminology "standardisation system" has been clarified and aligned throughout the document. The role of the Regulation within the broader European standardisation system has been explained in detail in the dedicated Section 2.1.2. This includes information on the business models of the ESOs and NSBs. Further details on funding of ESOs (through operating and action grants) has been presented in Section 3.1.1. In Section 4.1.1.1, it has been clarified in the text that there is

Points to improve	Follow-up
stakeholders to provide the right (and right amounts of) standards within an acceptable timespan. The root causes of any success or shortcoming should be identified. It needs to be clarified what the costs of harmonised standards development are and to what extent they are covered by the EU financing.	overall a strong incentive for ESOs to respond to standardisation requests and for national standardisation bodies to participate in the work due to the high intrinsic relevance of harmonised standards, yet with the Regulation only allowing standardisation requests to be addressed at the three ESOs (and not allowing the Commission to address the requests to other organisations that may be able to deliver faster), there may be a lack of an incentive for ESOs to adapt or accelerate their working methods. Additional analysis of root causes of key issues has been included, notably in the effectiveness conclusions (Section 4.1.1.6). More detailed figures on the funding of ESOs has been introduced in Section 3.1.2. In addition, the efficiency analysis outlines how certain costs for ESOs and Annex III organisations are covered by EU financing.
(2) The report needs to more clearly define **what would constitute a successful standardisation** to underpin EU policies and legislation, its expected impacts, and **by what criteria** it could be identified. The impacts regarding competitiveness need to be better assessed. It needs to be made clear to what extent the regulation contributes to the competitiveness of EU businesses including by the latter avoiding the cost of conformity assessments. In addition, the impact on innovation and international competitiveness should be further analysed. Any negative impacts on growth and competitiveness also need to be better assessed. Incorporating such aspects on growth and competitiveness, a full analysis of effectiveness and efficiency should be provided.	As a measure of success, the evaluation assesses whether standards that were requested by the Commission in accordance with the Regulation are delivered in an effective (i.e. meeting the requirements of the standardisation request), inclusive and timely manner, and whether the Regulation has been successful in reducing the delivery time. In Section 4.1.1.1, it has been assessed in different ways whether the Regulation has been successful in adequately reducing delivery time: first through stakeholder consultations (assessing the level of stakeholder satisfaction), second through a comparison with other (non-ESO) standardisation procedures, and third by assessing whether recent priority standards have been delivered. In addition, sectoral legislation has been analysed to identify the time between the date of application or date of transposition of the legislation and the delivery of the harmonised standard. Impacts on growth, innovation and competitiveness have been assessed in more detail in Section 4.1.1.5. This includes an analysis of sectoral evaluations to identify data on cost savings associated with the use of harmonised standards to ensure conformity of products and services (although only limited data is available). It has also been described how

Points to improve	Follow-up
	inefficiencies in the standard-development process (as described in Section 4.1) may hinder the Regulation's effectiveness in enhancing competitiveness in the Single Market and beyond.
(3) The intervention logic should be fully aligned with the scope and allow for operationalisation and assessment of objectives, outputs, outcomes and impacts. Steps in the causal chain of the intervention should be identified as clearly as possible. A comparative analysis with non-EU systems should be deepened aiming, among other things, to clarify evidence regarding root causes affecting effectiveness and efficiency.	The intervention logic has been further elaborated, in particular on the following aspects: (1) The scope of the evaluation has been clarified; (2) The intervention logic has been adjusted to include a clear definition of what is considered success in the implementation of the regulation; (3) The causal chains have been modified to take into account the horizontal nature of the regulation and the intrinsic importance of sectoral harmonised legislation (NLF) when assessing the outcomes and impacts of the regulation. In addition, a comparison with standardisation processes in the United States, China and Japan has been added in Annex X.
(4) The analysis of internal coherence needs to be strengthened. In particular, potential trade-offs between governance requirements and objectives should be analysed. The analysis of significance, root causes and consequences of increasing use of alternative routes should be improved.	The section on coherence was modified with more elements on internal coherence, in particular to highlight the trade-offs between main objectives of the regulation – speed of the standards development process, on one side, and the inclusiveness and participation of stakeholders in the process, on the other side. An analysis of the alternative routes has been included in the dedicated section 4.3.9.
(5) The methodological approach needs to be significantly strengthened. Analysis should be based on relevant financial data and representative sample(s) of businesses using standards and businesses involved in the development of harmonised standards. Results from nonrepresentative samples should not be extrapolated to the whole population. The analytical methods, in particular related to the analysis of costs and benefits, need to be based on verifiable assumptions.	It should be reiterated that the most significant challenge was the collection of verifiable quantitative data on certain aspects of the evaluation. In particular, no information is available to the Commission on the costs associated to purchase/use of standards. No literature is available, neither academic or grey literature, and no data have been collected. The original Impact Assessment has attempted to estimate the costs borne by businesses, but the methodology used was based on strong assumptions and provided mostly qualitative findings (no monetisation). Moreover, previous evaluation/monitoring exercises have not attempted to quantify costs according to Better Regulation Guidelines. As a result, there was a lack of a clear and robust baseline to rely on, and primary data collection was fundamental for the evaluation. For the reasons explained above, a mixed

Points to improve	Follow-up
	method approach was adopted, and the available evidence was triangulated to ensure, to the extent possible, the robustness of data. The limitations of the approach taken have been further explained. The costs borne by companies were included in (i) the public consultation, (ii) targeted surveys and (iii) interviews.
(6) In case the evidence base is not significantly strengthened, the conclusions should clearly acknowledge the lack of evidence and related uncertainties. The existing monitoring and reporting arrangements should be critically analysed to draw appropriate lessons for future monitoring. It needs to be analysed to what extent the reporting under the regulation delivers data that are needed to assess the functioning of the regulation.	The conclusions have been modified to reflect the limitations in terms of data availability. Opportunities for improved monitoring and reporting (while avoiding unnecessary reporting burdens) have been recognised in the text.
(7) Based on the analysis of underlying structures and processes the full potential for simplification and burden reduction needs to be assessed in addition to the potential of digitisation.	The analysis of simplification and burden reduction has been moved to the dedicated Section 4.1.2.4. This includes a broader assessment of future simplification opportunities (as far as an *ex post* evaluation allows).

Table 9: Comments from the second RSB opinion on the draft SWD

Points for improvement	Follow-up
(1) The conclusions should better reflect the results of the analysis including on low quality of draft standards, the effectiveness of the Annex III organisations participation, trade-offs between the objective of accelerating standards development and increasing inclusiveness, the need for skills to effectively participate and the consequences of the recent rulings of the Court of Justice regarding access to standards,	The conclusions have been redrafted. The quality issues (combined with the reinforced role of the Commission in line with ECJ judgements), the effectiveness of Annex III organisations, the importance of skilled experts and the impact of the ECJ judgements have been explicitly mentioned. The trade-off between speed and inclusiveness is also mentioned, although it should be recognised that speed and inclusiveness can go hand-in-hand when reducing the complexity of standard-development processes and thereby removing a barrier for effective stakeholder participation.
(2) Notwithstanding the acknowledgement in the conclusions that there is a need for more effective monitoring and reporting arrangements, the arrangements under the existing regulation are not sufficiently analysed to allow concrete lessons to be	A dedicated paragraph on monitoring and reporting arrangements has been added to the section on lessons learnt (Section 5.2), including references to specific data gaps. These data gaps have also been recognised in the effectiveness and efficiency sections.

Points for improvement	Follow-up
drawn for future monitoring and reporting to assess the functioning of the regulation. The lessons learned should detail what data are needed including regarding the costs to stakeholders and effects on competitiveness to assess the effectiveness and efficiency of ESS in the future.	However, while we can acknowledge these data gaps, reporting burden should be avoided when seeking to fill these gaps. This evaluation cannot pre-empt any policy decision on future monitoring and reporting requirements.
(3) The problems with the existing business model in terms of lack of incentives for the European Standardisation Bodies (ESOs) to adapt or accelerate their working methods, e.g. limited digitisation, is acknowledged in the report and reflected in the conclusions. However, it is argued that the "significant relevance" or "high intrinsic relevance" of harmonised standards are a strong incentive for the ESOs to work on the development and delivery of these standards. It should be clarified whether this is expected to constitute a genuine incentive to ensure timely high-quality delivery.	It is clarified in the text (Section 4.1.1.1) that - despite the general intrinsic relevance of harmonised standards- ESOs depend on the willingness of stakeholders to contribute to speedy standard-development, which may vary. Furthermore, given the lack of alternatives for the Commission, there may also be a lack of an incentive for ESOs to adapt or accelerate processes.
(4) The assessment of competitiveness-related impacts should be improved. The analysis should not be based on expected benefits from Impact Assessment(s) or general academic studies, but on the assessment of benefits actually observed in the evaluation period, specifically benefits that result from the harmonised standards that follow from the regulation (as contrasted with other standards). The impact on innovation should be further elaborated, including impacts on product differentiation.	The text (Section 4.1.1.5) contains all available evidence on competitiveness impacts, based not only on secondary sources but also on stakeholder consultations. A survey conducted with companies and interviews with business organisations at EU level enabled triangulation of the data from secondary sources. While the direct impact on competitiveness remains unclear, there is clear evidence that in many sectors hENs have an effect in long-term growth and foster innovation in products and services. Nevertheless, it must be recalled that the Regulation only sets the horizontal framework for the development of harmonised standards and thereby supports sectoral or product legislation, hence its contribution to economic impacts (including competitiveness) should be considered an indirect effect of its application. The main difference between harmonised standards and other standards relates to the legal value of harmonised standards and the associated presumption of conformity, which results in cost savings for businesses. This has been highlighted in the text. With regard to product differentiation, there was no relevant evidence or concern raised by

Points for improvement	Follow-up
	stakeholders. Standards have a voluntary nature and ENs and hENs serve the purpose of easing the process of technical compliance with minimum requirements established by the law. Accordingly, from a theory-based perspective, product differentiation is not expected to be affected by the Regulation as it can still happen – despite the hENs are adopted – in the production of a certain product. This may be the reason why the relationship between product differentiation and hENs is unexplored and it would require new research to establish if this is a relevant impact to be assessed.
(5) The intervention logic should more clearly analyse how the achievement of the specific objectives is expected to lead to the achievement of the competitiveness aspects of the overall objectives. Besides quick delivery time of standards other aspects of effects on competitiveness also need to be analysed.	The relation between the specific objectives and the broader impacts on competitiveness and growth has been clarified. Besides the speed of standardisation, the quality of harmonised standards also plays a role, as reflected in Section 4.1.1.1.
(6) The perceived cost-benefit ratios derived from a non-representative sample of opinion data cannot be used as an equivalent substitute to an actual cost-benefit analysis and does not sufficiently underpin conclusions about the cost-effectiveness or proportionality of the intervention. As far as possible, information regarding the full costs of the intervention, including costs accruing to stakeholders, should be collected and analysed.	As part of the evaluation study, all costs accrued to the stakeholder groups involved in the ESS were mapped and estimated. All the three ESOs and all the four Annex III organisation were involved in consultations as well as the European Commission (both for data collection and validation of the results). With regard to industry stakeholders and businesses, an actual cost-benefit analysis was not feasible. However, the methodological approach applied allows us to draw some conclusions on the importance of benefits and the magnitude of costs, despite a limited number of replies to the survey. The analysis was validated with representative industry organisations at the EU level.
(7) In terms of readability the report exceeds the recommended page limits, and should be significantly shortened, with a focus on retaining the most relevant information.	The report has been shortened, while retaining the additional data gathered to address comments of the Regulatory Scrutiny Board.
(8) The changes to the report, including changes on conclusions, should be reflected in the executive summary.	The executive summary has been revised.

ANNEX II: METHODOLOGY AND ANALYTICAL MODELS USED

This Annex describes the methodology used to conduct the research for this staff working document and the underpinning study. The first part summarises all the activities conducted. The second part describes the analytical model used for quantitative estimations reported for the "efficiency" criterion.

Activity 1: Inception

Sub-activity 1.1: Review and completion of theoretical framework

This sub-activity focused on reviewing and finalising the theoretical framework through preliminary desk research and scoping interviews, resulting in the intervention logic, the evaluation grid, and the consultation strategy and tools. The preliminary desk research covered the EU policy framework, reporting, guidelines and supporting studies, as well as academic studies.

Ten scoping interviews were conducted to engage key stakeholders in developing the evaluation process. The interviews were designed to be semi-structured. The subjects discussed included the effectiveness, efficiency, relevance, coherence, and the added value the Regulation brings to the EU. A list of questions targeted to each interviewee was shared prior to the discussion. Minutes have been drafted for these interviews.

Sub-activity 1.2: Consultation strategy

Sub-activity 1.2 involved the development of an approach to implement the consultation strategy.

Consultation methods were aligned with the evaluation criteria to ensure that comprehensive answers to all evaluation questions and primary data can be obtained.

Stakeholder mapping

From the key findings of the inception phase, ten stakeholder sub-categories were identified within four main target categories for consultations:

- **Legislative and Policy Actors:** These include EU institutions and national authorities that shape and execute policies at both levels.
- **Technical Actors:** These comprise International Standardisation Bodies, European Standardisation Organisations (ESOs), and National Standardisation Bodies, which are crucial for developing and overseeing standards.
- **Industrial and Societal Stakeholders**: This group represents industrial sectors through associations, industry groups, companies at various levels, and organisations for SMEs, consumers, environmental, and social interests.
- **Experts:** Made up of academic experts, and researchers like those from the Joint Research Centre (JRC), providing valuable analytical insights on EU standards.

Allocating stakeholders to the consultation approach

Considering the refined goals of the consultation tools and the characteristics of the identified stakeholders, such as the size of the group and their role within the European Standardisation System, each stakeholder sub-category was matched with the most appropriate consultation method.

Stakeholders' engagement strategy

The Study Team has employed the following approach to enhance response rates and bolster the evidence base:

- **Established networks** were contacted (e.g. High-Level Forum on European Standardisation, European Standardisation Panel Survey, Multi-Stakeholder Platform on ICT Standardisation, the European Commission) and enhanced reach-out through a snowballing effect.
- **Direct e-mails to representatives of main groups,** particularly industry associations at the EU and national levels, including those representing SMEs, and a published list of authorities involved.
- **Internal network of the Consortium**: Consortium members have a well-established network of contacts in the standardisation ecosystem which will be contacted to reach out to all relevant stakeholders.

Activity 2: Data collection activities

Sub-activity 2.1: In-depth desk research

Data was gathered according to relevant criteria, evaluation questions, and indicators. The documents reviewed include:

- Secondary sources, particularly:
    - Evaluation documents produced for the European Commission.
    - Article 24 Reports
    - European Commission Database on EN, harmonised standards and standardisation requests
    - Case law of the Court of Justice of the European Union.
    - Academic papers and reports.
- Position papers shared by stakeholders, including those shared during the "Call for Evidence period".[225] Stakeholder feedback is assumed to present views that are relevant to assess the landscape of opinions on the topic.

Sub-activity 2.2: Public Consultation and Call for evidence

A public consultation was conducted by the European Commission from 2 May 2024 to 25 July 2024. The Call for evidence was conducted by the Commission from 1 September 2023 to 29 September 2023.

The public consultation received 253 valid replies.[226] Specifically, 63 respondents (25%) were from business associations, while 58 respondents (23%) represented companies or businesses. Other notable groups included respondents categorised as "Other" (29 respondents, 11%), public

[225] The Call for Evidence was open in the period 01 September 2023 - 29 September 2023 (midnight Brussels time) on the "Have Your Say" portal. See at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13446-European-standardisation-evaluation_en

[226] The total number of replies submitted amount at 255, but 2 replies were identified as duplicates, and they were removed from the analysis

authorities (27 respondents, 11%), and non-governmental organisations (NGOs) with 24 respondents (10%).

EU citizens contributed with 17 responses (7%), while trade unions accounted for 14 responses (6%). Smaller groups included academic or research institutions (9 respondents, 4%), consumer organisations (8 respondents, 3%), non-EU citizens (3 respondents, 1%), and environmental organisations, with just one respondent.

90 valid replies were submitted to the Call for evidence:[227]

- Business Associations: 34 responses (37.78%)
- Non-governmental Organisations (NGOs): 12 responses (13.33%)
- Other: 11 responses (12.22%)
- Companies/Businesses: 10 responses (11.11%)
- EU Citizens: 10 responses (11.11%)
- Public Authorities: 7 responses (7.78%)
- Consumer Organisations: 2 responses (2.22%)
- Academic/Research Institutions: 2 responses (2.22%)
- Environmental Organisations: 1 response (1.11%)
- Trade Unions: 1 response (1.11%)

Regarding the respondents' country of origin in the Call for evidence, Belgium had the highest response rate with 35 responses (38.7%). France and Germany followed, each contributing 9 responses (10%), while the United States submitted 7 responses (7.8%). Sweden and Italy each accounted for 6 responses (6.7%), while Slovakia, Portugal, and Finland each had 3 responses (3.3%). The Netherlands, Denmark, and Austria contributed 2 responses each (2.2%). Finally, Slovenia, Poland, Latvia, Lithuania, Ireland, Spain, Switzerland, and Bulgaria each had 1 response, representing 1.1% each.

While the call for evidence provided useful evidence that added to the analysis, most stakeholders provided the same feedback in the Public consultation. Therefore, the following sections will focus more on the results of the latter.

Limitations

- **Lack of statistical representation**: the main limitation of the data from the Public Consultation (PC) is their lack of statistical representation of the wider population, making the analysis purely descriptive. The data reflect only the views of respondents in this sample.
- **Sample size limitations for some groups**: additionally, the sample size issue highlights that groups like academia, NGOs, and public authorities have lower response rates than others. This was mitigated via interviews.

[227] European Commission. (n.d.). European standardisation - evaluation. Retrieved November 7, 2023, from https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13446-European-standardisation-evaluation/feedback_en

- **Bias from coordinated campaigns**: some coordinated campaigns were detected. These were properly disclosed and analysed.

Sub-activity 2.3: Targeted Surveys

As a follow-up to the public consultation, via surveys specific questions were posed to (i) NSBs/NCs/NSOs (ii) industry organisations and companies and (iii) Annex III organisations. The three surveys were conducted online from July to August 2024.

Survey design

Three questionnaires were developed, tailored to three specific groups of respondents. These consisted mainly of closed questions using Likert-scale items and numeric queries, along with open-ended questions. Closed questions facilitated quantitative analysis to identify trends across stakeholder groups, while open-ended questions allowed for detailed and unique feedback, ensuring that all viewpoints were considered. **The surveys aimed, among other activities, to gather data for a cost-benefit analysis, using self-reported estimates of FTEs, hours worked, and costs of labour and additional expenses**.

The surveys were pilot tested before they were disseminated to ensure that the questions were clear, relevant, and capable of capturing comprehensive data.

A total of 50 responses were received in the industry and companies survey, including one submission from the Annex III organisation, SBS-Small Business Standards. Among the submitted responses, 52% were from companies/businesses and 48% were industry associations. All four Annex III organisations replied to the targeted Annex III survey. A total of 22 NSBs from across the European Union participated in the targeted NSB survey, representing a diverse range of countries.

Limitations

- **Lack of statistical representation**: the main limitation of the data from the survey is their lack of statistical representation of the wider population, making the analysis purely descriptive. The data reflect only the views of respondents in this sample.
- **Sample size limitations for some groups**: additionally, the sample size issue highlights that some countries have lower response rates than others. This was mitigated with interviews.
- **Challenges in collecting cost data:** some stakeholders expressed concerns over providing their company's cost data in the survey as they consider it sensitive information.
- **Potential outliers:** Due to the sample size limitations, outliers have a greater influence over the distribution of data. This was mitigated by outlier deletion.

Sub-activity 2.4: Interviews

Interviews with key stakeholders had two objectives: (i) to **fill data gaps identified in the desk research** and (ii) **deepen the analysis of contexts and causes** of key issues identified. Interviews were conducted from August 2024 to October 2024.

Interview design

A single template was created for the gap-filling interviews, while multiple templates were prepared for the in-depth interviews. These templates followed a semi-structured format, divided into sections corresponding to each evaluation criterion.

- For the gap-filling interviews, data gaps were identified and mapped to the evaluation questions. Relevant stakeholders were then designated for each identified data gap.
- For the in-depth interviews, distinct templates catered to each stakeholder category.

Once stakeholder availability was confirmed, templates were customised for each one.

Interview dissemination

Respondents from the public consultation who showed interest in interviews were listed. Their categories were reviewed and the total proportion of representation by both country and category was calculated. This provided a basis for selecting the stakeholders to invite for interviews.

- For gap-filling interviews, the study team had already identified stakeholders using a data gap matrix.
- For in-depth interviews, the study team ensured that stakeholder selection maintained a balanced representation across all categories.

The focus was on targeting underrepresented categories in the public consultation both by country and by category.

Response rate

A total of 46 interviews were conducted.

Table: List of interviews conducted by stakeholder group

Stakeholder group	Number of interviews
European Commission experts	3
International Standardisation Bodies	1
European Standardisation Organisations (ESO)	2
Annex III organisations	4
National authorities	2
National Standardisation Bodies	1
HAS Consultants	1
National Accreditation Body	1
Member of Annex III organisation	1
Trade and business associations	16
Companies / Businesses	10
Academia, research institutes and think tanks	4
Total	46

Activity 3: Data analysis

Sub-activity 3.1: Analysis and answers to evaluation questions

Sub-activity 3.1 consisted of the analysis of data gathered through the previous activities to provide clear and evidence-based findings.

Analysis of desk research

Secondary sources were analysed following a mixed-method approach. **The policy documents, reports and studies underwent a thorough review using a two-step coding system**. First, the research team marked sections of text based on specific evaluation questions and indicators. After

this initial coding, the data were examined again using new codes. These new codes were created by finding and grouping similar ideas and meanings across different sections.

A Study database was created to collect all quantitative data from available datasets and reports (e.g. Article 24 Reports).

Call for Evidence, public consultation (PC) and survey analysis

As per Better Regulation Guidelines, the Study team adopted a systematic approach to clean the data, consisting of four key steps:

1. Correction of category identification mistakes
2. Removal of duplicates
3. Handling of NA values
4. Detection of outliers and errors

Campaign analysis

Following the Better Regulation Guidelines, campaign responses were evaluated by examining individual replies from various respondents within the same stakeholder group. During the Call for Evidence no coordinated campaign was observed. During the public consultation on Regulation 1025/2012:

- 13 nearly identical responses were received for the open question: To what extent has Regulation (EU) 1025/2012 achieved its general objectives?
- 12 nearly identical responses were received for the open question: To what extent are you satisfied with the development time of EU harmonised standards?

Overview of the analysis

The Call for Evidence data implied a qualitative analysis. For the PC and the targeted surveys, survey data were compiled in Excel files by creating tabs for different questionnaire sections, such as demographics and themes like inclusiveness or timeliness. Tables were used to quickly summarise key metrics for categorical (e.g. yes/no), Likert scale (e.g. agree-disagree), and complex questions. When multiple Likert scales were used for statements, each statement was analysed separately.

Data analysis

The subsequent phase entailed an in-depth analysis of the cleansed data, with responses categorised according to various demographics like stakeholder type and country. Where relevant, the analysis used descriptive statistics such as counts, percentages, means, and medians, especially for numerical questions. Open-ended responses were summarised thematically and, where needed, further delineated by stakeholder groups to identify trends in qualitative feedback.

Reporting

The reporting phase focused on transforming the results into narrative as well as tables and graphical visualisations to ensure clarity and accessibility. Tables were used to present percentages, counts, and subgroup analysis, particularly for questions measured on scales, allowing

comparisons between different response groups. Visualisations, such as stacked bar charts for Likert scale questions and histograms for numerical responses, were employed to convey the results graphically, supporting easier interpretation.

Interview analysis

Interviews were analysed through a two-phase coding system. Initially, the consultants highlighted text sections according to particular evaluation questions and indicators. Following this initial coding, the data were re-examined with new codes that were developed by identifying and grouping similar ideas and meanings across various responses.

Data triangulation

The triangulation was structured according to the evaluation questions and indicators, putting together all the data gathered through previous activities (in-depth desk research, stakeholder consultations) in order to establish the evidence base.

A matrix was developed to compare the evidence per question from the different sources and cross-analyse the findings in order to identify patterns and address each strategic question.

Analysis of the speed of the process linked to activity 4: Standardisation requests (Article 10 of Regulation (EU) No. 2015/2012).

The European Commission maintains records of key dates and timestamps to track the process duration. These are guided by the Vademecum SWD (2015) 205 (final Part 2) which indicates the dates and timestamps to be recorded. These data are collected by the European Commission in three internal databases[228]:

- **SIGNIFERI**: this database contains dates for Phase A – the process of drafting and adopting mandates of the standardisation requests by the European Commission. The data cover the years between 2014 and 2024.
- **eNorm**: this database contains additional dates for Phase A. Specifically it stores the date of adoption of the mandates and the dates of the deadlines for delivery. The data covers the years between 2014 and 2024.
- **HAS database**: this database concerns dates for Phase C. Regarding Phase B, the database collects the dates of adoption of a harmonised standard by the ESOs. With regards to Phase C, the HAS database contains the dates of submission to the Commission and the publication dates in the OJEU. The data cover the years between 2019 and 2024.

Methodology and analytical models used for the efficiency assessment

Introduction

This second part of the Annex explains in detail all the calculations done for the analysis reported under the "efficiency" criterion.

[228] The overview of the databases highlights important dimensions for the evaluation of the duration of the process. First, the data do not cover the entire period from 2012 to 2024. In particular, the data on publication dates in the OJEU only cover the period from 2019 and 2024. On the contrary, data on phase B - i.e. the time between when an ESO accepts a request, covers the period between 2009 – 2024.

Identification and mapping the costs and benefits of the Regulation against Better Regulation guidelines

As a first step, costs and benefits have been mapped following the typology provided by the Better Regulation toolbox (Tool 76) during the inception phase. The model has been further refined through desk research and validation with stakeholders.

Costs

Compliance costs

Direct compliance costs of the Regulation are the costs for stakeholders that are directly linked to the provisions of the Regulation. The provisions of the Regulation 1025/2012 generate the following costs:

- Article 24 generates administrative, and reporting requirements costs for Annex III organisations and administrative and reporting requirements costs for European Standardisation Bodies (ESOs)
- Article 3 and Article 4 generates administrative, and reporting requirements costs for European Standardisation Bodies (ESOs) and for National Standardisation Bodies (NSBs/NCs/NSOs)
- Article 6 generates administrative, and reporting requirements costs for National Standardisation Bodies (NSBs/NCs/NSOs)
- Articles 13 and 14 generate administrative costs for identifying common ICT technical specifications under the process established by article 13 and 14 of the Regulation 1025/2012
- Articles 8, 10 and 16 generate administrative and reporting requirements costs for the European Commission.

Indirect compliance costs

In line with the Better Regulation Guidelines, indirect costs typically arise from changes in the prices, quantity, or quality of goods and services in the regulated sector. The Regulation itself does not impose indirect compliance costs if we interpret the definition of indirect costs strictly according to the Guidelines.

However, the European Standardisation System involves various stakeholders whose involvement incurs certain costs. Unlike direct compliance costs, which stem from stakeholders adhering to requirements set out by the Regulation, participation costs are voluntary. In practice, though, stakeholders invest substantial resources in participating in the development and revision of standards, so these can be seen as indirect costs of the Regulation.

Regulation 1025/2012 establishes a framework for European standards as requested by the European Commission, influencing the number of standards created. While participation in standardisation activities under Regulation 1025/2012 requires considerable investment, it remains a voluntary choice for stakeholders. For this reason, these are categorised as indirect costs: they result from Commission requests for standards and the choice of organisations to engage in their

development or revision. It should be noted, however, that the definition of indirect costs used in this analysis differs slightly from that in the Better Regulation Guidelines (BRG).

The indirect costs associated with these standards result from stakeholders voluntarily contributing to hENs' development, revision and purchasing them. These include:

- Participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables for Annex III organisations.
- Participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables for businesses.
- Costs of purchasing harmonised standards for businesses.

Opportunity costs

Opportunity cost refers to the cost associated with foregoing alternative investment options. Regulation 1025/2021 highlights this by introducing an opportunity cost linked to selecting different types of conformity assessments.

When businesses bring products to market, they can choose from various conformity assessment procedures. Within the EU, they may use harmonised standards to benefit from a presumption of conformity or rely on notified bodies to verify their products' compliance with regulations. In other regions outside Europe, different conformity assessments are employed, which also generate opportunity costs. Thus, opportunity costs are:

- **EU opportunity cost of conformity assessments**: Opportunity cost of using voluntary harmonised standards compared to using other conformity assessment procedures in the EU market.
- **Global market opportunity cost of conformity assessments**: Opportunity costs of using voluntary harmonised standards in the EU market compared to using other conformity assessment procedures in third countries markets.

Benefits

Direct regulatory benefits

Direct regulatory benefits are benefits generated by the impact of the Regulation. The study shows that Regulation 1025/2012 generates an increase in welfare, specifically:

- Increase in welfare of consumers
- Increase in welfare of the environment
- Increase in welfare of workers
- Direct economic benefits

The table below illustrates the identification of costs and benefits against the typology provided by Better Regulation guidelines.

Table:- Identification and mapping of costs and benefits

Category	Group	Subgroup	Identification
Costs	Direct costs of the Regulation	*Direct compliance costs*	▪ Administrative, reporting requirement costs for Annex III organisations

			▪ Administrative and reporting requirements costs for National Standardisation Bodies (NSBs) ▪ Administrative and reporting requirements costs for European Standardisation Bodies (ESOs) ▪ Administrative, and reporting requirements costs for the European Commission. ▪ Costs of identifying common ICT technical specifications under the process established by article 13 and 14 of the Regulation 1025/2012
		Enforcement costs	NA
		Hassle costs	
	Indirect costs of the Regulation	*Indirect compliance costs*	*NA but given the voluntary participatory nature of the ESS, stakeholders invest considerable resources related to standards developed upon Commission request:* ▪ Participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables for Annex III organisations ▪ Participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables for businesses ▪ Costs of purchasing harmonised standards for businesses *These should not be considered as strictly indirect compliance costs, but as indirect costs of the Regulation.*
		Offsetting/substitution costs	NA
		Transaction costs	NA
		Opportunity costs	▪ Opportunity cost of using harmonised standards compared to using other conformity assessment procedures in the EU market. ▪ Opportunity costs of using harmonised standards in the EU market compared to using other conformity assessment procedures in third countries markets.
		Negative impacts on market functioning	▪ Affordability of standards for SMEs ▪ Compliance with regulatory obligations based on standards in the construction sector ▪ Negative externalities on the environment ▪ Free riding
Benefits	Direct regulatory benefits	*Increase in welfare*	▪ Increase in welfare of consumers ▪ Increase in welfare of the environment ▪ Increase in welfare of workers ▪ Direct economic benefits
		Market efficiency improvements	NA
	Indirect regulatory benefits	*Indirect compliance benefits*	NA
		Wider macroeconomic benefits	NA
		Other non-monetary benefits	NA

Data collection on costs

Direct compliance costs

Annex III organisations and ESOs

Data regarding administrative and reporting requirement costs for Annex III organisations and ESOs were gathered from the study on the implementation of Regulation (EU) No.

1025/2012 (Article 24) conducted in 2021, and it dates back to 2020.[229] In the study, data on labour costs for ESOs are reported as missing for 2020, thus they were collected from the study on the implementation of the Regulation conducted in 2015.[230] 2024 data on person-days were shared by the ESOs.

The studies use activity-based micro-costing techniques that listed categories of reporting requirements and asked stakeholders to estimate the number of labour days, labour costs per day and frequency per year of the activities. The activities are reported in the following table.

Table: Administrative and reporting requirements for Annex III organisations and ESOs.

Type of obligation	Description of the required action(s)	Entity
Reporting on the implementation of the Regulation (Article 24)	Collection of the input from the NSBs/NSOs	ESOs
	Drafting of the Article 24 report to be submitted to the EC	ESOs
	Drafting of the Article 24 report to be submitted to the EC	Annex III organisations
Financing of standardisation activities (Art. 15 and Art. 17) – Operating grants	Drafting of the action plan (i.e. work programme related to the operating grant)	ESOs
	Final and interim reporting related to operating grant	ESOs
	Drafting of the action plan (i.e. work programme related to the operating grant)	Annex III organisation
	Final and interim reporting related to operating grant	Annex III organisations
Financing of standardisation activities (Art. 15 and Art. 17) – Action grants	Drafting of the proposal for one action grant (average time)	ESOs
	Final and interim reporting related to one action grant (average time)	ESOs
Standardisation requests (Art. 10.5)	Annual reporting on the execution of a standardisation request (regardless the request for financing)	ESOs

National Standardisation Bodies

Data on reporting requirements costs for National Standardisation Bodies (NSBs/NCs/NSOs) collected through targeted surveys of National Standardisation Bodies (NSBs/NCs/NSOs). Using an activity-based micro-costing technique, categories of reporting requirements tasks that National Standardisation Bodies (NSBs/NCs/NSOs) use were listed. These were asked to estimate the number of full-time-equivalents that they employ on the activity on average in a year and the working days to complete the tasks. The sample size is 19 National Standardisation Bodies (NSBs/NCs/NSOs).

For National Standardisation Bodies (NSBs/NCs/NSOs) participation in seven activities corresponding to discrete activities performed by National Standardisation Bodies in the process was examined.

A. Requesting other standardisation bodies' draft standards for review.

B. Commenting on requested drafts of standards.

[229] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020, 2022, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2022:30:FIN

[230] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and EY, Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24) – Final report, Publications Office, Luxembourg, 2021a, https://data.europa.eu/doi/10.2873/504681

C. Addressing comments from other Standardisation bodies on requested drafts of standards.

D. Sharing best practices with other National Standardisation Bodies to involve SMEs in standardisation activities.

E. Drafting Work Programmes.

F. Notification of Work Programmes to the ESOs, European Commission and Member States.

G. Reporting duties set in the Regulation

Indirect compliance costs

Employing an activity-based micro-costing approach involved modelling activity categories and gathering data from stakeholders on the specific resources consumed, such as labour, materials, and equipment for each activity.

For businesses, participation was modelled in five activities corresponding to discrete activities performed by companies in the process.

A. Proposal and acceptance process of new work items

B. Participation in technical discussions on proposals

C. Submission of comments on draft standards or deliverables

D. Revision of existing European standards or deliverables

We collected participation costs using targeted surveys. Data for SMEs consist of a subset of 31 responses to the targeted survey of industry from medium-sized (50 to 249 employees), micro (1 to 9 employees), and small (10 to 49 employees) companies, representing 62% of the sample. Data for large businesses comprise a subset of 19 responses to the targeted survey of industry from large companies (250 or more) which corresponds to 38% of the total survey sample.

Industry stakeholders were asked to estimate for a single standard a year the average number of full-time-equivalents that they employ on the activity, the hourly labour costs, the average number of TCs/WGs, and the ancillary costs (travels, meals, materials, etc.).

For Annex III organisations, participation costs were collected using targeted surveys. Organisations were asked to estimate for a single standard per year the average number of full-time-equivalents that they employ on participation in technical discussions. Prior to the analysis outlier tests on the data were not conducted because the sample used is complete with all observations. Some assumptions were made regarding the average hourly labour costs, average number of meetings per TC, average ancillary costs.

Opportunity costs

We collected data on two opportunity costs:

- **EU opportunity cost of conformity assessments**: Opportunity cost of using voluntary harmonised standards compared to using other conformity assessment procedures in the EU market.

- **Global market opportunity cost of conformity assessments**: Opportunity costs of using voluntary harmonised standards in the EU market compared to using other conformity assessment procedures in third countries markets.

With regard to the EU opportunity cost of conformity assessments, data were collected through targeted surveys of businesses through stated preference techniques (see Better Regulation Toolbox TOOL #57, Box 8), with a sample size of 17 companies. Companies were asked to value a series of percentage decreases in time of development and citation in the OJEU of standards to compute a willingness to pay (WTP).

Concerning the global market opportunity cost of conformity assessments, data were collected through the targeted survey on using other conformity assessment procedures in third countries markets compared to the cost of using voluntary harmonised standards in the EU market. Participants were asked to indicate the percentage difference between costs of EU conformity assessments using harmonised standards and the costs of conformity assessments in Canada, China, Korea, Japan, South Africa and the United States. The sample size is 49 companies.

Data collection on direct regulatory benefits

Direct regulatory benefits are benefits generated by the impact of the Regulation. The evidence shows that Regulation 1025/1025 generates an increase in welfare, specifically:

- Increase in welfare of consumers
- Increase in welfare of the environment
- Increase in welfare of workers
- Direct economic benefits

Generally, such benefits can be estimated using monetary values through market and non-market valuation approaches. However, there is not enough data to use such approaches. Therefore, a 1 to 5 scoring approach to estimate benefits was used.

Data for the perceived benefits for society were collected from the targeted surveys of Annex III organisations questionsQ18, Q19, Q20, Q21. The questions asked respondents to rate a benefit on a scale from 1 to 5, with 1 corresponding to “very low” to 5 corresponding to “very high”.

Data for the perceived benefits for society were collected from the targeted surveys of industry questions Q14 and Q35 with a sample size of 49 companies responding to the questions. The questions asked respondents to rate their agreement with statements corresponding to a benefit on a scale from 1 to 5, with 1 corresponding to “strongly disagree” to 5 corresponding to “strongly agree”.

The table below lists the benefits rated.

Table: List of benefits rated by stakeholders.

Stakeholders	Benefits
Society	• Safety of consumers • Alignment with intended uses • The reliability of the system's operation and its quality assurance protocols • The influence on consumers resulting from the attention given to the certification mark • Promotion of environmental sustainability • The impact on broader environmental policymaking due to the role of harmonised standards in the EU
SMEs and large businesses	• Representation at the political level • Representation of sector-specific issues. • Contribution with industry expertise • Development and implementation of standards • Facilitation of cross-border Trade • Market penetration for innovations • Cost reduction for production • Increased product interoperability • Enhanced company growth and competitiveness • Competitiveness via conformity presumption • Competitiveness through common ICT Standards

Data wrangling

Before the data analysis, the data collected has been cleaned and adjusted to ensure a robust analysis.

Inflation adjustments

Data regarding administrative and reporting requirement costs for Annex III organisations and ESOs have been adjusted to EU inflation, using the Eurostat Harmonised Index of Consumer Prices (HICP).[231] The formula used is:

Formula 6-1. Inflation adjustment

$$\boldsymbol{Adjusted\ cost = Cost_{t0} * (1 + Average\ Inflation\ Rate)^{n}}$$

Where:

- $\boldsymbol{Cost_{t0}}$ is the original cost at the former year value.
- $\boldsymbol{Average\ Inflation\ Rate}$ is the average of the inflation rate from $\boldsymbol{t0}$ to $\boldsymbol{t1}$
- $\boldsymbol{n}$ is the number of years from $\boldsymbol{t0}$ to $\boldsymbol{t1}$

Survey wrangling

Data collected from surveys for businesses and National Standardisation Bodies (NSBs/NCs/NSOs) underwent a standard approach of analysis to mitigate inherent problems with self-reported survey data on costs. Small sample non stratified survey data pose several challenges for cost benefits analysis. Data for Annex III organisations do not follow this approach because the sample size corresponds to all the four organisations and there are no missing data. Small and unrepresentative samples can result in significant variance from the population mean. Moreover, self-reported cost data have several biases:

- **Selection bias**: respondents who provide cost data tend to have similar characteristics that can skew data

[231] Eurostat: Online data code: prc_hicp_manr, DOI:10.2908/prc_hicp_manr, last update:01/10/2024

- **Memory and inaccuracy bias**: respondents may forget or provide inaccurate information often based on heuristics and outdated information.
- **Survey comprehension**: respondents may not fully understand the scope of the survey and provide other information.

This was mitigated through piloting surveys, however given these challenges several procedures to minimise bias were adopted, obtaining robust results. The process is described in the sections below.

Outlier detection and assessment

Outliers were identified using the following procedure:

- Calculated the arithmetic mean of data
- Calculated the standard deviation of data
- Calculate the Z-score for each data point
- Interpreted the Z-scores: Z-scores above 3 or below -3 indicate potential outliers.

Significant outliers in business data, specifically in the responses provided by SMEs were detected. Data for SMEs comprise a subset of 31 responses of the targeted survey of industry from medium-sized (50 to 249 employees), micro (1 to 9 employees), and small (10 to 49 employees) businesses, representing 62% of companies. There are 49 outlier observations in responses from SMEs over 499 observations, corresponding to approximately 10% of the observations.

Data for large businesses constitute a subset of 19 responses to the targeted survey of industry from large companies (250 or more) which correspond to 38% of the total survey sample. There are 29 outliers in the responses from large companies. For National Standardisation Bodies (NSBs/NCs/NSOs) we identified 20 outliers over 311 observations. Correspondingly approximately to 6% of the observations.

Outlier rates of 10% and 6% can generate large variability in cost data.

Mitigation

Due to the outliers multiple approaches were used to mitigate the influence of outliers and test the statistics on the sensitivity of values to methods:

- **Original data:** the original data was used to compute standard deviations and standard errors to examine the variability of the data.
- **Winsorisation**: it limits the effect of outliers in a dataset by replacing them with the nearest values within a defined percentile range, rather than removing them, thereby capping extreme values to lessen their impact. Data at the 10th and 90th percentiles were winsorised. If a value was less than the 10th percentile, it was replaced with the 10th percentile. If the value was more than the 90th percentile it was replaced with the 90th percentile. Standard deviations and standard errors were computed to examine the variability of the data.
- **Monte Carlo distribution**: a Monte Carlo simulation was used on 10 000 observations to generate a range of possible outcomes of the winsorised data to quantify the uncertainty of the estimates of the two data.

To estimate, both arithmetic and geometric means were used to assess the impact of outliers. The geometric mean finds the central tendency of numbers by multiplying them and then taking the n-th root (where n is the number of values). The geometric mean is generally lower than the arithmetic mean unless all values are equal. This happens because the geometric mean accounts for the effect of outliers differently, reducing the impact of large values.

Cost-benefit scores standardisation

To compare the costs and benefits on the same scale the costs on a scale from 1 to 5 were standardised to create a consistent framework for comparison against non-monetary benefits, using the following formula:

Formula 6-2. Cost-benefit scores standardisation

$$\boldsymbol{Standardised\ Cost} = \frac{\boldsymbol{Xmax - Xmin}}{(\boldsymbol{X - Xmin})} \times \mathbf{4} + \mathbf{1}$$

Where:

- $\boldsymbol{X}$ represents the specific cost being standardised.
- $\boldsymbol{Xmax}$ is the maximum value in the dataset, or the highest cost observed.
- $\boldsymbol{Xmin}$ is the minimum value in the dataset, or the lowest cost observed.
- ($\boldsymbol{Xmax - Xmin}$) calculates the range of the dataset, which is the difference between the maximum and minimum values.
- ($\boldsymbol{X - Xmin}$) calculates how far the specific value X is from the minimum value. This helps in determining where stands within the range from minimum to maximum
- $\frac{\boldsymbol{Xmax-Xmin}}{(\boldsymbol{X-Xmin})}$ this fraction scales the distance of X from the minimum value relative to the entire range. It effectively places on a proportionate scale based on the spread of values in the dataset.
- $\boldsymbol{\times 4 + 1}$ scales and shifts the standardised cost onto a specific range. Multiplying by 4 adjusts the standardised value to fit a range from 1 to 5, and adding 1 shifts the starting point so that the lowest possible value is 1 instead of 0.

The formula standardises any value within the range onto a scale from 1 to 5. A lower input value will result in a standardised cost closer to 1, while a higher value will be scaled closer to 5.

Data analysis

Cost formulae

The formulae used to calculate the costs in the analysis is provided. Please note that both the arithmetic average and the geometric average are computed to compare the impact of variance on central tendency.

Administrative, reporting requirement costs for Annex III organisations

Adjusted costs of the 2020 assessment.

Administrative and reporting requirements costs for National Standardisation Bodies (NSBs)

Formula 6-3. Administrative and reporting costs for NSBs

$$\sum_{i=1}^{n}(\boldsymbol{Average\ FTEs\ Actvity_i} * \boldsymbol{Average\ Working\ Days_i} * \boldsymbol{Average\ Daily\ Labour\ Cost})$$

Where:

- $\boldsymbol{Average\ FTEs\ Actvity_i}$ represents the average annual full-time equivalent for activity i.
- $\boldsymbol{Average\ Working\ Days_i}$ represents the average working days for activity i.
- $\boldsymbol{Average\ Daily\ Labour\ Cost}$ represents the average working days for activity i.
- $\boldsymbol{n}$ is the total number of activities.

Administrative and reporting requirements costs for European Standardisation Bodies (ESOs)

Adjusted costs of the 2020 assessment with 2024 person-days data.

Willingness to pay to reduce time of development of harmonised standards

Formula 6-4. WTP for time reduction in harmonised standards development

$$\frac{1}{n}\sum_{i=1}^{n}(\boldsymbol{WTP\ for\ a\ percentage\ change\ reduction\ in\ time\ of\ development_n})$$

Where:

- $\boldsymbol{WTP\ for\ a\ percentage\ change\ reduction\ in\ time\ of\ development_n}$ is the total value that the stakeholders would be willing to pay for a percentage reduction in time
- $\boldsymbol{n}$ is the percentage reduction of 10%, 25%, 50% and more than 50%.

In practice this means summing up the investments for each percentage change reduction and calculating the average.

Willingness to pay to reduce time of citation in the OJEU of harmonised standards

Formula 6-5. WTP for time reduction in harmonised standards citation in the OJEU

$$\frac{1}{n}\sum_{i=1}^{n}(\boldsymbol{WTP\ for\ a\ percentage\ change\ reduction\ in\ time\ of\ citation\ in\ the\ OJEU_n})$$

Where:

- $\boldsymbol{WTP\ for\ a\ percentage\ change\ reduction\ in\ time\ of\ citation\ in\ the\ OJEU_n}$ is the total value that the stakeholders would be willing to pay for a percentage reduction in time
- $\boldsymbol{n}$ is the percentage reduction of 10%, 25%, 50% and more than 50%.

In practice this means summing up the investments for each percentage change reduction and calculating the average.

Participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables for Annex III organisations

Formula 6-6. Average costs of participating in technical work for a single Annex III organisation

$$\frac{1}{n}\sum_{i=1}^{n}((\mathbf{FTE} * \boldsymbol{Average\ Hourly\ Labour\ Costs}) + \boldsymbol{Average\ ancillary\ cost}\mathbf{s})) * \boldsymbol{Average\ TCs/WGs_i}$$

Where:

- $\boldsymbol{FTEs}$ represents the average full-time equivalent for the activity for one standard per year.
- $\boldsymbol{Average\ Hourly\ Labour\ Cos}$t represents the average hourly cost for the activity for one standard per year assuming a value of EUR 195 based on interview data.
- $\boldsymbol{Average\ Number\ of\ TC\ Meetings}$ represents the average number of technical committees' meetings participated in a year assuming a value of 30 from interview data.
- $\boldsymbol{Average\ Ancillary\ Cost}$s represent the average cost of meals, travels, materials for activity A for one standard) assuming a value of EUR 800 based on interview data.
- $\boldsymbol{Average\ TCs/WGs}$ represents the average annual number of TCs/WGs reported for each Annex III organisation
- $\boldsymbol{n}$ is the total number of Annex III organisations.

Participation in the technical work with respect to the development and revision of European standards and European standardisation deliverables for businesses

Formula 6-7. Average costs of participating in technical work for a single business

$$\sum_{i=1}^{n}((\boldsymbol{Average\ FTEs\ Actvity_i} * \boldsymbol{Average\ Hourly\ Labour\ Cost_i}) + \boldsymbol{Average\ ancillary\ costs_i})) * \boldsymbol{Average\ TCs/WGs}$$

Where:

- $\boldsymbol{Average\ FTEs\ Actvity_i}$ represents the average full-time equivalent for activity i for one standard per year.
- $\boldsymbol{Average\ Hourly\ Labour\ Cost_i}$ represents the average hourly cost for activity i for one standard per year.
- $\boldsymbol{Average\ ancillary\ costs_i}$ represent the average cost of meals, travels, materials for activity i for one standard).
- $\boldsymbol{Average\ TCs/WGs}$ represents the average annual number of TCs/WGs reported.
- $\boldsymbol{n}$ is the total number of activities.

Please note that for activity B. For participation in technical discussions on proposals, the following formula has been applied:

Formula 6-8. Costs of participating in technical work – Businesses, Activity B

$$(\boldsymbol{Average\ FTEs\ Actvity_B} * \boldsymbol{Average\ Hourly\ Labour\ Cost_B} * \boldsymbol{Average\ Number\ of\ TC\ Meetings_B} *) + \boldsymbol{Average\ Ancillary\ Costs_B}$$

Where:

- $\boldsymbol{Average\ Number\ of\ TC\ Meetings_B}$ represents the average number of meetings per TC for a single standard in a year.

Costs of harmonised standards for businesses

This is calculated taking the average of the costs of purchase and subscription.

Global market opportunity cost of conformity assessments

The survey collected data on respondents' expectations regarding differences in costs for six countries: United States, Canada, Japan, Korea, China, and South Africa. Respondents indicated the likelihood of different cost change scenarios, ranging from "10% cheaper" to "100% more expensive", including an option for "same cost". Each country had a unique distribution of percentages reflecting the proportion of respondents selecting each scenario in costs differences. Each scenario in costs differences (e.g. 10% cheaper, 20% cheaper, 30% more expensive) was assigned a corresponding value ranging, e.g. -10% (representing a response indicating "10% cheaper") to +10% (representing a response indicating "10% more expensive").

The next step involved calculating the weighted average cost difference for each country. The percentages of respondents selecting each scenario were multiplied by the corresponding cost change value, and the results were summed to obtain the overall expected cost for each country.

The formula used was as follows:

Formula 6-9. Global market opportunity cost for conformity assessments

$$\sum_{i=1}^{n} (\boldsymbol{Percentage\ Change_i} * \boldsymbol{Cost\ Change_i})$$

Where:

- $\boldsymbol{Percentage\ Change_i}$ is the proportion of respondents who selected cost change (e.g. 8% for 10% cheaper).
- $\boldsymbol{Cost\ Change_i}$ is the corresponding cost change (e.g. -10% for 10% cheaper).
- $\boldsymbol{n}$ is the total number of cost change scenarios.

For each country, the weighted contributions of all cost change scenarios were summed. This produced an average expected cost for each country. This process was repeated for all cost change scenarios, and the resulting values were summed to compute the average cost.

Costs sensitivity analysis

The sensitivity analysis for SMEs shows that the estimates using the original data are very sensitive to outliers. In contrast, the winsorised data show less variation. Monte Carlo analysis confirms that the optimal choice of estimate is the arithmetic mean of winsorised data.

Table:- Sensitivity analysis for SMEs participation costs in the development and revision of European standards and standardisation deliverables

Method	Statistics	Mean, lower, upper limit	Average annual cost for one TC/WG	Average annual cost across all Technical Committees (TCs) and Working Groups (WGs).
Original dataset	Arithmetic mean	Mean	€ 38,021.82	€ 330,930.68
Original dataset	Geometric mean	Mean	€ 11,367.19	€ 74,659.50
Winsorised	Arithmetic mean	Mean	€ 6,523.52	€ 141,826.22
Winsorised	Geometric mean	Mean	€ 8,003.99	€ 50,216.32
Monte Carlo with winsorised	Arithmetic mean	Mean	€ 8,170.06	€ 62,551.93
Monte Carlo with winsorised	Geometric mean	Mean	€ 8,966.31	€ 72,991.98

Similarly, the sensitivity analysis for large companies shows that the estimates using the original data are very sensitive to outliers. In contrast, the winsorised data show less variation. Monte Carlo analysis confirms that the optimal choice of estimate is the Arithmetic mean of winsorised data.

Table:- Sensitivity analysis for Large businesses' participation costs in the development and revision of European standards and standardisation deliverables

Method	Statistics	Mean, lower, upper limit	Average annual cost for one TC/WG	Average annual cost across all Technical Committees (TCs) and Working Groups (WGs).
Original dataset	Arithmetic mean	Mean	€ 21,820.20	€ 2,060,796.93
Original dataset	Geometric mean	Mean	€ 6,749.92	€ 105,325.14
Winsorised	Arithmetic mean	Mean	€ 12,773.07	€ 237,011.39
Winsorised	Geometric mean	Mean	€ 4,627.56	€ 53,652.77
Monte Carlo with winsorised	Arithmetic mean	Mean	€ 12,705.67	€ 232,515.00
Monte Carlo with winsorised	Geometric mean	Mean	€ 14,036.26	€ 250,291.08

For NSBs the sensitivity analysis reveals high sensitivity to outliers but capping data through winsorisation removes all the variance in the data. Therefore, the optimal methodological choice is to use the geometric mean of the original data.

Table:- Sensitivity analysis for National Standardisation Bodies' administrative and reporting costs

Method	Statistics	Annual cost
Original data	Arithmetic mean	€ 14,347,079.91

Original data	Geometric mean	€ 123,713.05
Winsorised data	Arithmetic mean	€ 1,400.00
Winsorised data	Geometric mean	€ 1,400.00
Monte Carlo simulation	Arithmetic mean	€ 1,400.00
Monte Carlo simulation	Geometric mean	€ 1,400.00

Cost benefit ratios

To compare costs and benefits on the same scale, costs were standardised to a 1 to 5 scale, creating a consistent framework for evaluating non-monetary benefits using this formula:

$$\boldsymbol{Standardised\ Cost} = \frac{\boldsymbol{Xmax - Xmin}}{(\boldsymbol{X - Xmin})} \times \mathbf{4} + \mathbf{1}$$

Cost benefit ratios were then calculated:

Formula 6-10. Cost benefit ratio

$$\boldsymbol{Cost\ benefit\ ratio} = \frac{\boldsymbol{Benefit}}{\boldsymbol{Cost}}$$

Therefore:

- Cost benefit ratio = 1 indicates that the benefit is proportional to the cost
- Cost benefit ratio > 1 indicates that the benefit is greater than the cost
- Cost benefit ratio < 1 indicates that the benefit is lower than the cost

Costs validation with stakeholders

As part of the evaluation study, two rounds of cost validation were conducted with industry representatives[232], ESOs and Annex III stakeholders. We presented the estimates individually to representatives of each stakeholder group. We asked them to discuss the estimated costs to:

- Assess the accuracy of the estimates in terms of order of magnitude
- Provide additional data to contextualise the findings
- Suggest any shortcomings of gaps in the analysis

The results of the sensitivity analysis were presented to industry representatives, requesting their feedback on which estimation method yielded the most accurate outcomes. There was consensus among the industry representatives that the method identified by the study team, following statistical analysis, was the most reliable.

Validation with ESOs offered additional insights to contextualise the estimated costs and identified gaps in the cost assessments.

Lastly, validation involving Annex III organisations led to the development of a more robust methodology for assessing participation costs. Given these organisations' business structures, the initial estimation method aligned with industry practices was revised for greater accuracy. Furthermore, a focus group with Annex III organisations was conducted to gather final inputs on cost assessments.

[232] Business Europe and SBS.

ANNEX III: EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

The following table provides the evaluation matrix used for the Evaluation. Answers to each evaluation question and sub-question are provided in the main text, section 4.

EQ	Sub-question	Judgment Criteria	Indicators	Data sources
Effectiveness				
EQ1. To what extent has the Regulation 1025/2012 achieved its objectives related to the standardisation process in enhancing speed of European standards setting processes?	**EQ1.1.** Has the time to develop and cite in the OJEU a harmonised standard decreased under the Regulation following the adoption of procedures of Standardisation requests (Article 10)?	The correct execution of the process laid out in Article 10 of the Regulation 1025/2021 regarding Standardisation requests to European standardisation organisations has contributed to increase the speed of standards development.	➢ Number of harmonised standards developed under the Regulation. ➢ Estimate of time to produce harmonised standards, (where feasible with a breakdown of specific activities). ➢ Level of satisfaction of stakeholders with time to develop standards. ➢ Estimate of time for citing standards in the OJEU once the Commission issues a positive assessment of harmonised standards	○ Database review of EC *eNorm Platform, European Commission standardisation requests* database. ○ Database review of Eur-Lex: Implementing Decisions of the Commission publishing the European Standards in the OJEU of the EU ○ Database review of CEN/CENELEC *Standards Evolution and Forecast* database. ○ Database review of ETSI *Portal Work Programme (IT tool)* database ○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs) ○ Desk research on monitoring, reporting and guideline sources. ○ Desk research on position papers (Industry associations). ► Interviews with ESOs. ► Targeted survey of Industry Associations. ► Targeted surveys of National Standardisation Bodies.

				► Targeted survey of Annex III organisations.
	EQ1.2. Is the current governance in the European Standardisation system experienced as an accelerator or slowing down the standardisation process?	Processes of the EU standardisation governance contributed to accelerating the speed of standards development.	➢ Governance processes that contributed directly to accelerating the speed of standards development. ➢ Barriers in governance processes that slowed down the speed of standards development.	○ Desk research on position papers. ○ Desk research on monitoring, reporting and guideline sources. ► Interviews with ESOs. ► Interviews with Industry Associations. ► Targeted survey of Industry Associations. ► Targeted surveys of National Standardisation Bodies.
	EQ1.3. Is the potential of ICT tools fully used in the delivery process of standardisation post Regulation?	ICT tools are fully exploited in standardisation processes at ESOs level, and they have increased the speed of the standardisation process.	➢ Number of ICT tools used by ESOs by type. ➢ Amount of time saved per task using ICT tools.	○ Desk research on academic and study sources. ○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs). ○ Desk research on position papers (Industry associations, SBS). ► Interviews with ESOs. ► Targeted survey of Industry Associations.
EQ2. To what extent has the Regulation 1025/2012 achieved its objectives in enhancing stakeholder participation in European Standardisation?	**EQ2.1.** Have ESOs encouraged and facilitated the effective participation of the diverse range of stakeholders identified in the Regulation in their standardisation activities?	ESOs have encouraged and facilitated the representation and effective participation of a diverse range of stakeholders, including SMEs, consumer organisations, and environmental and social stakeholders, in their standardisation activities.	➢ Number and percentage of stakeholders per category participating in the proposal and acceptance of new work items. ➢ Number and percentage of stakeholders per category participating in the technical discussion on proposals. ➢ Number and percentage of stakeholders per category participating in the submission of comments on drafts. ➢ Number and percentage of stakeholders per category participating in the revision of existing European standards or	○ Desk research on monitoring, reporting and guidelines: yearly reporting of Annex III organisations. ○ Desk research on position papers (Annex III organisations). ○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs) ○ Desk research on academic and study sources. ► Interviews with ESOs. ► Targeted survey of Industry Associations.

			European Standardisation deliverables. ➢ Number and percentage of stakeholders per category participating in the dissemination of information and awareness-building about adopted European Standards or European standardisation deliverables. ➢ Level of satisfaction of stakeholders with their level of involvement and participation in the development of standards ➢ Reported level of accessibility of processes, documents, meetings, websites, materials, events	► Targeted survey of Annex III organisations.
	EQ2.2. Are the harmonised standards widely accepted by businesses and consumers?	There is evidence that standards are widely accepted by both businesses and consumers.	➢ Level of use of harmonised standards by businesses and consumers. ➢ Number of international standards adapted by ESOs into harmonised standards within a given timeframe. ➢ Ratio of harmonised standards with modifications to those adopted without changes.	○ Desk research on position papers (Industry associations). ○ Desk research on position papers (SBS, ANEC). ► Interviews with ESOs ► Targeted survey of Industry Associations ► Targeted survey of Annex III organisations: SBS, ANEC
	EQ2.3. Have ESOs encouraged and facilitated the effective representation at a technical level of research undertakings, research centres, universities and other non-industrial legal entities, in standardisation activities concerning an emerging area with significant policy or technical innovation implications (Article 5, (2))?	ESOs have encouraged and facilitated the representation and effective participation at a technical level of undertakings, research centres, universities, and other legal entities, in standardisation activities concerning an emerging area with significant policy	➢ Number and percentage of stakeholders per category participating at a technical level in standardisation activity concerning an emerging area with significant policy or technical innovation implications. ➢ Qualitative assessment of barriers and challenges to effective participation of stakeholders in standardisation activities concerning an emerging area with significant policy or technical innovation implications.	○ Desk research on position papers (Industry associations, scientific organisations). ○ Database review on ESOs websites ○ Desk research on monitoring, reporting and guidelines: ESOs. ► Interviews with ESOs ► Public Consultation

	or technical innovation - implications	➢ Qualitative assessment of incentives for effective participation of stakeholders in standardisation activities concerning an emerging area with significant policy or technical innovation implications.	
EQ2.4. Have NSBs encouraged and facilitated participation of the diverse range of relevant stakeholders identified in the Regulation in their standardisation activities?	Participation and inclusiveness of all relevant stakeholders at EU and national levels including Market Surveillance Authorities and Notified Bodies is ensured in the standardisation processes.	➢ Level of compliance of NSBs with the principles of the Regulation concerning stakeholder participation and access to draft national standards (Article 4). ➢ Level of compliance of NSBs with the principles of the Regulation concerning exchange of information (Article 4). ➢ Level of compliance of NSBs with the principles of the Regulation concerning the independence of the NSBs. ➢ Level of compliance of NSBs with the principles of the Regulation concerning facilitating access of SMEs (Article 6).	○ Desk research on monitoring, reporting and guidelines: annual work programmes (NSBs) ○ Desk research on monitoring, reporting and guideline sources. ○ Database review on NSBs websites. ► Interviews with NSBs ► Targeted consultation of Annex III organisations
EQ2.5. Is the notification and the information contained in NSBs and ESOs work programmes available, accessible and of good quality as required by Article 3?	The notification process and the quality of information contained in the work programmes established by European standardisation organisations and national standardisation bodies is transparent.	➢ Percentage of European standardisation organisations and national standardisation bodies that notify the existence of their work programmes within the specified timeframe. ➢ Number of work programmes that include the complete set of information as mandated by Article 3 ➢ Number of work programmes available on public websites and the frequency of updates to these online resources. ➢ Stakeholder feedback on the clarity, detail, and usefulness of	○ Desk research on monitoring, reporting and guidelines: annual work programmes (NSBs) ○ Database review on NSBs websites. ► Targeted survey for Industry Associations ► Targeted survey for Annex III organisations

			the information provided in the work programmes. ➢ Reported user experience to gauge the ease of accessing and understanding the work programmes on public websites. ➢ Stakeholder feedback on their awareness of and engagement with the work programmes' notification process.	
	EQ2.6 Is the elaboration of the annual Union Work programmes effective in view of its objectives (Article 8)?	The annual Union Work programmes meet their objectives as outlined in Article 8.	➢ Number of standards developed or initiated in alignment with priorities. ➢ Number of specific objectives and policies defined for standard development. ➢ Stakeholder satisfaction regarding the relevance of standards to the defined objectives and policies. ➢ Number of urgent standard requests issued by the Commission. ➢ Number of objectives set for the international dimension of standards. ➢ Level of stakeholder engagement measured by participation rates in consultations. ➢ Diversity of stakeholder representation in consultation processes. ➢ Stakeholder satisfaction with Commission's guidance in the standardisation process.	► Interviews with ESOs ► Targeted survey for National Standardisation Bodies ► Targeted survey for Industry Associations ► Targeted survey for Annex III organisations
EQ3. To what extent has the Regulation 1025/2012 achieved its objectives related to broaden the use of "fora	**EQ3.1.** Are the ICT technical specifications identified so far effective in enhancing	ICT technical specifications enhance interoperability in public procurement and facilitate seamless integration and	➢ Level of reference of ICT technical specifications in public procurement by the EU national authorities. ➢ Benefits of referencing ICT technical specifications in public	○ Desk research on monitoring, reporting and guidelines: annual work programmes (NSBs). ○ Desk research on position papers (Industry associations, Fora and consortia, public authorities).

and consortia" technical specifications in public procurement?	interoperability in public procurement?	compatibility across different systems and services used within the public sector.	procurement by the EU national authorities. ➢ Quality of requirements for the identification of ICT technical specifications that are listed in Annex II. ➢ Bottlenecks in the process for the identification of ICT technical specifications.	○ Desk research on monitoring, reporting and guideline sources. ○ Database review on NSBs websites ► Gap-filling interviews with European multi-stakeholder platform on ICT standardisation ► Targeted survey of Industry Associations ► Interviews with fora and consortia developing ICT standards
	EQ3.2. Are there any impacts of the use in EU legislation of ICT technical specifications beyond the area of Public Procurement as an alternative to European standards by the ESOs or to international standards?	ICT technical specifications in EU legislation outside of public procurement supplement or substitute European standards or international standards where appropriate.	➢ Number of EU legislative acts that reference ICT technical specifications as opposed to European or international standards. ➢ The proportion of ICT technical specifications that have been adopted as a supplement or substitute to existing standards. ➢ The percentage of stakeholder groups (e.g. industry experts, consumer associations) that recognise the ICT technical specifications as effective substitutes or supplements. ➢ Adoption rate by industry sector. ➢ Adoption rate by SMEs. ➢ Comparison of level of interoperability between products developed using ICT technical specification and those developed with European or International standards. ➢ Comparison of barriers to market entry when using ICT technical specifications with those when	○ Desk research on monitoring, reporting and guidelines: "*The Rolling Plans for ICT Standardisation.*" ○ Desk research on position papers (Industry associations, Fora, and consortia). ○ Desk research on EC policy framework: "DG CNECT: Work Programme 2020-2024" ► Targeted survey of Industry Associations ► Targeted survey of Annex III organisations ► Gap-filling interviews with European multi-stakeholder platform on ICT standardisation

			using European or International standards. ➢ Reasons for adopting ICT technical specifications.	
EQ4. To what extent has the Regulation achieved its objectives related to removing ambiguities in the legal framework?	**EQ4.1.** Is the formal objections (Article 11) mechanism effective?	The formal objection mechanisms ensures that the process for procedures is streamlined across harmonised standards.	➢ Number of formal objections raised since the applicability of the Regulation by Member States and European Parliament ➢ List of outcomes of formal objections raised since the applicability of the Regulation by Member States and European Parliament.	○ Review of DG GROW internal database on formal objections ○ Desk research on monitoring, reporting and guidelines: "*Report by the Commission on the Standardisation Regulation – 2022*" ○
	EQ4.2. Is the coordination and cooperation between ESOs and national bodies throughout the standardisation request process effective in removing national conflicting standards?	There is evidence that the level of collaboration and coordination between ESOs and NSBs during the standardisation request process contributes to removing conflicting standards.	➢ Percentage of idiosyncratic national standards. ➢ Rate of withdrawal of conflicting national standards within a specified reasonable deadline after a new harmonised standard is published. ➢ Number of reported cases where NSBs took actions that could potentially prejudice the harmonisation intended during or after the preparation of harmonised standards. ➢ Stakeholder perceptions of any challenges or successes in the harmonisation process due to NSB actions. ➢ NSB practices during the harmonisation process to identify patterns of behaviour that either support or hinder the ESOs' harmonisation efforts. ➢ Assessments of the procedures and timeliness employed by NSBs to withdraw conflicting national standards, including the effectiveness of communication to	○ Database review on academic and study sources. ○ Desk research on monitoring, reporting and guideline sources: "*Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States*." ○ Desk research on monitoring, reporting and guideline sources ○ Desk research on position papers (Industry associations). ○ Desk research on monitoring, reporting and guidelines: annual work programmes (NSBs). ○ Database review on EU institutions websites. ► Interviews with ESOs ► Targeted surveys of National Standardisation Bodies

			relevant stakeholders about these withdrawals.	
EQ5. What are the economic and social impacts of the Regulation 1025/2012 on the internal market, consumers' safety, workers' protection, and environmental protection?	**EQ5.1.** To what extent has the Regulation contributed to better functioning of the internal market, by supporting the EU legislation?	EU standards are used, and quality level of standards is in line with market needs.	➢ Trade volume within EU, including: (i) product categories in the EU market covered by harmonised standards, (ii) share of product categories placed in the EU market using harmonised standards, (iii) share of products placed in the EU market using non-harmonised standards[233] ➢ ➢ Number of harmonised standards aligned with Commission's policy objectives. ➢ Percentage of industry associations and companies, including SMEs, considering harmonised standards in line with market needs	○ Database review on EU institutions websites. ○ Desk research on position papers (Industry associations, SBS). ○ Desk research on monitoring, reporting and guideline sources: "*Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States*." ► Interviews with ESOs ► Targeted survey of Industry Associations ► Targeted survey of Annex III organisations: SBS ► Interviews of Annex III organisations: SBS ►
	EQ5.2. Do harmonised standard contribute to facilitate growth, innovation and increase competitiveness of European businesses, especially SMEs?	Harmonised standards contribute to increase EU competitiveness of businesses and SMEs in the EU market and in the global market	➢ Trade volume within EU and extra-EU, including: (i) product categories in the EU market covered by harmonised standards, (ii) share of product categories placed in the EU market using harmonised standards, ➢ Percentage of industry associations and companies, including SMEs, considering harmonised standards relevant to increase competitiveness, as a results of: (i) use of the presumption of conformity of harmonised standards, (ii) use of common ICT	○ Database review on EU institutions websites. ○ Desk research on position papers (Industry associations, SBS). ○ Desk research on monitoring, reporting and guideline sources: "*Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States*." ► Interviews with ESOs

233 At the current stage, we estimate to collect these data through targeted surveys, as no public database collects the exact figures.

		technical specifications in public procurement, (iii) enhanced innovation	► Targeted survey of Industry Associations ► Targeted survey of Annex III organisations: SBS ► Interviews with Annex III organisations: SBS
EQ5.3. Does the application of harmonised standards – in conjunction with the manufacturers' self-assessment and, where applicable, the conformity assessment performed by notified bodies – provide consumers' safety, workers' protection, and environmental protection?	Voluntary harmonised standards, coupled with manufacturers' self-assessment and conformity assessments by notified bodies offer comparable safety, health, and environmental protection outcomes.	➢ The number of incidents or safety violations reported for products certified under voluntary harmonised standards versus those certified under mandatory technical regulations. ➢ The rate of compliance or non-compliance findings in audits or assessments for products adhering to voluntary harmonised standards. ➢ The percentage of products undergoing self-assessment and notified body assessments that meet or exceed regulatory safety and health benchmarks. ➢ The percentage of harmonised standards that directly refers to the protection of the environment. ➢ The reduction in environmental impact or improvement in sustainability metrics for products assessed under voluntary harmonised standards compared to those under traditional regulatory assessment frameworks.	○ Database review on EU institutions websites. ○ Database review: ISO survey of certifications of management standards. Desk research on position papers (ANEC, ETUC, ETUI, ECOS) ○ Desk research on monitoring, reporting and guideline sources, ○ Desk research on monitoring, reporting and guidelines: annual work programmes. ► Interviews with ESOs ► Targeted survey of Annex III organisations
EQ5.4. Do harmonised standards developed by ESOs produce modifications to international standards?	Harmonised standards developed by ESOs introduced modifications on international standards.	➢ The ratio of harmonised standards with modifications to those adopted without changes. ➢ The percentage of modifications proposed by ESOs that are accepted at the international level.	○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs) ○ Desk research on academic and studies sources. ○ Desk research on position papers (International standardisation bodies).

				► Interviews with technical actors Interviews with Int. Standards bodies
Efficiency				
EQ6. How cost-efficient are the administrative processes and reporting requirements for different parties generated by Regulation 1025/2012?	**EQ6.1.** Are the costs of stakeholder engagement and participation in the European Standardisation System for ESOs, NSBs and the Commission proportionate to their benefits?	The costs for stakeholders to engage and participate in the European Standardisation System with ESOs, NSBs and the Commission are proportionate to the benefits.	➢ Costs of SMEs engagement and participation for NSBs, broken down by: ➢ Costs of access to working documents ➢ Costs of participation in technical committees ➢ Costs of participation in working groups ➢ Costs of communication development and delivery ➢ Costs of submitting opinions on draft standards ➢ Formal arrangement costs (meetings, travel costs, training material, office supplies, meals, event planning, including costs for ensuring accessibility to persons with disabilities) ➢ Costs of sharing best practices of SMEs engagement and participation for NSBs, broken down by: ➢ Costs of communication development and delivery ➢ Formal arrangement costs (meetings, travel costs, training material, office supplies, meals, event planning, including costs for ensuring accessibility to persons with disabilities)	○ Desk research on monitoring, reporting and guidelines: annual work programmes (NSBs) ○ Desk research on monitoring, reporting and guideline sources: "*Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States*." ► Interviews with ESOs ► Interviews with the Commission ► Targeted surveys of NSBs ► Targeted surveys of Annex III organisations

			➢ Costs of societal organisations (Annex III) engagement and participation for ESOs, broken down by:
			  ➢ Costs of access to working documents
			  ➢ Costs of participation in technical committees
			  ➢ Costs of participation in working groups
			  ➢ Costs of communication development and delivery
			  ➢ Costs of submitting opinions on draft standards
			  ➢ Formal arrangement costs (meetings, travel costs, training material, office supplies, meals, event planning, including costs for ensuring accessibility to persons with disabilities)
			➢ Costs of research undertakings engagement and participation with ESOs for the Commission.
			➢ Benefits of stakeholders' participation broken down by:
			  ➢ Benefits for the environment (emissions, pollution, energy efficiency)
			  ➢ Benefits for workers' welfare and conditions
			  ➢ Benefits for consumers' safety
			  ➢ Benefits for SMEs' economy
			➢ Cost/benefit ratios.
			➢ Cost savings ratios.	

			➢ Stakeholders' perception on cost-benefit proportionality.	
	EQ6.2. Are the costs of identifying ICT technical specifications proportionate to its benefits?	The costs of identifying ICT technical specifications are proportionate to its benefits.	➢ Costs of identification for the Commission and Member States. ➢ Costs of consultation with the European multi-stakeholder platform on ICT standardisation. ➢ Cost/benefit ratios. ➢ Cost savings ratios. ➢ Stakeholders' perception on cost-benefit proportionality.	○ Desk research on monitoring, reporting and guidelines: annual work programmes (NSBs). ○ Desk research on monitoring, reporting and guidelines: stakeholder platform on ICT standardisation. ► Interviews with ESOs, because some have liaisons with IEEE. ► Gap-filling interviews with European multi-stakeholder platform on ICT standardisation
	EQ6.3. Are the costs of cooperation between ESOs, NSBs and the Commission proportionate to its benefits?	The costs of cooperation between ESOs, NSBs, and the Commission are proportionate it its benefits.	➢ Costs of commenting on requested drafts of standards for ESOs, NSBs, and the Commission. ➢ Costs of addressing comments for ESOs, NSBs. ➢ Cost/benefit ratios. ➢ Stakeholders' perception on cost-benefit proportionality.	○ Desk research on monitoring, reporting and guidelines: *Annual reports from the ESOs to the Commission.* ► Interviews with ESOs and NSBs ► Interviews with the Commission ► Targeted surveys of National Standardisation Bodies
	EQ6.4. Are any aspects of the European Standardisation System disproportionately burdensome in terms of administrative and reporting requirements on stakeholders and/or other actors?	Administrative and reporting requirements of the European Standardisation System impose proportionate burden in terms of their costs and benefits.	➢ Costs of Standardisation Bodies work programmes. ➢ Costs of notification of Standardisation Bodies work programmes to ESOs, NSBs, Commission and Member States. ➢ Costs of annual Union Work programmes. ➢ Costs of Reporting on the implementation of the Regulation 1025/2012 (Article 24). ➢ Costs of Financing of standardisation activities (Art. 15 and Art. 17)-Operating grants.	○ Database review on EU institutions websites ○ Database review on NSBs websites ○ Desk research on position papers (Industry associations, Annex III organisations). ○ Desk research on monitoring, reporting and guideline sources: *Annual reports from the ESOs to the Commission.* ○ *Desk research on Evaluation of the Single Market Programme*

		➢ Costs of Financing of standardisation activities (Art. 15 and Art. 17)- Action grants. ➢ Costs of Standardisation requests (Art. 10.5). ➢ Cost/benefit ratios. ➢ Stakeholders' perception on cost-benefit proportionality.	*(running in parallel with this Study)* ► Interviews with ESOs ► Targeted surveys of National Standardisation Bodies ► Targeted survey of industry associations ► Targeted survey of Annex III organisations ► Interviews with Annex III organisations
EQ6.5. Are there redundancies or bottlenecks in the administrative procedures that could be streamlined to improve efficiency?	There are no redundancies in the administrative and reporting requirements and the procedures impose an administrative burden that it is proportionate to its benefits.	➢ Number of administrative and reporting requirements that have a disproportionate cost/benefit ratio. ➢ Number of identified redundancies in the administrative and reporting requirements. ➢ Number of administrative and reporting requirements that could be modified to achieve a proportionate cost/benefit ratio. ➢ Number of administrative and reporting tasks that are semi-automated or fully automated. ➢ Number of administrative and reporting tasks that are not automated and that can be semi-automated or fully automated.	○ Database review on EU institutions ○ Database review on NSBs websites ○ Desk research on academic and studies ○ Desk research on monitoring, reporting and guideline sources: *Annual reports from the ESOs to the Commission.* ○ Desk research on monitoring, reporting and guideline sources: *Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24)* ► Interviews with ESOs ► Targeted surveys of National Standardisation Bodies ► Targeted survey of Industry Associations ► Targeted survey of Annex III organisations ► Interviews with Annex III organisations

EQ7. How cost-efficient is the development of 'harmonised standards' and 'European standardisation deliverables' throughout the process of standardisation requests?	**EQ7.1.** What are the costs of standard setting for different parties of the process?	The costs of standard setting are proportionate to the benefits of standard setting for parties in the process.	➢ Costs of making standards, using the following parameters: (1) average number of produced standards per year; (2) average number of meetings to finalise a EU standard; (3) average duration of those meetings; (4) average number of delegates attending those meetings; (5) average hourly cost of each delegate; (6) average ancillary costs (e.g. travel, ESOs' support, location rental if appropriate); (7) any other average cost with a significant relevance. ➢ Difference in average costs by topic and level of complexity of standardisation process. ➢ Pre and post COVID-19 difference in costs assessing savings from virtualisation of the meetings. ➢ Stakeholders' perception on cost-benefit proportionality.	○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs). ○ Desk research on monitoring, reporting and guidelines: annual Union work programmes (EC). ○ Desk research on position papers (Industry associations, Annex III organisations). ○ Desk research on monitoring, reporting and guideline sources: *Annual reports from the ESOs to the Commission.* ○ Desk research on monitoring, reporting and guideline sources: *Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24).* ► Targeted survey of Industry Associations ► Interviews with ESOs ► Interviews with Industry Associations ► Interviews with EU Commission
	EQ7.2. Are the costs for manufacturers of placing products through voluntary harmonised standards proportionate to the benefits?	There is a reduction of manufacturing costs for businesses when placing products on the market through voluntary harmonised standards.	➢ Manufacturing costs for manufacturers when placing products on the market through self-assessment by referring to voluntary harmonised standards. ➢ Manufacturing costs for manufacturers when placing products on the market through self-assessment by referring to technical specifications such as national standards, non-harmonised European and international standards, or the	○ Desk research on position papers (Industry associations, SBS). ○ Desk research on academic and study sources ► Targeted survey of Industry Associations ► Targeted survey of SBS, representing SMEs

		manufacturer's own technical specifications. ➢ Manufacturing costs for manufacturers when placing products on the market through conformity assessment via Notified Bodies. ➢ Cost ratios between placing products through voluntary standards and self-assessment, and other conformity assessment procedures. ➢ Costs incurred by the same manufacturers in certain other countries and regions (e.g. US, Canada, Japan, Korea) where the products are placed on the markets via technical regulations and type approval. ➢ Stakeholders' perception on reduction of manufacturing costs.	
EQ7.3. To what extent the Regulation generated cost and benefits on specific product categories, on the main sectors impacted by the Regulation (e.g. ICT Public Procurements, Machinery, Services,) or on new technology areas (e.g. Artificial Intelligence, Cybersecurity, data, cleantech)?	The costs of standard setting for the specific product categories, on the main sectors impacted by the Regulation (e.g. ICT Public Procurements, Machinery, Services,) or on new technology areas (e.g. Artificial Intelligence, Cybersecurity, data, cleantech) are proportionate to the benefits generated.	➢ Number of standards produced in the product categories on the main sectors impacted by the Regulation and on new technology areas (Artificial Intelligence, Cybersecurity, data, cleantech). ➢ Costs of standards produced in the specific product categories, on the main sectors impacted by the Regulation and on new technology areas (Artificial Intelligence, Cybersecurity, data, cleantech). ➢ Level of adoption of standards produced in the specific product categories, on the main sectors impacted by the Regulation (e.g. ICT Public Procurements, Machinery, Services,) or on new technology areas (Artificial	○ Database review on recent studies on standardisation ○ Desk research on position papers (Industry associations, Annex III organisations). ○ Database review on sectoral studies ► Targeted survey of industry associations ► Interviews with industry associations ► Interviews with experts

			Intelligence, Cybersecurity, data, cleantech). ➢ Cost/benefit ratios.	
	EQ7.4. Is the Union financing to the ESOs cost-efficient compared to the ESOs outputs in support of EU policies and legislation? (Articles 15-17)	Union financing to ESOs is proportionate to the outputs produced by ESOs under standardisation requests.	➢ Costs identified in EQ 7.1 ➢ Costs of EU deliverables which are a transposition of an international standard. ➢ Costs of EU deliverables which are not a transposition of an international standard. ➢ Average cost per unit of EU deliverables produced by ESOs.	○ Desk research on monitoring, reporting and guidelines: annual work programmes of the ESOs ► Interviews with ESOs ► Interviews with EU Commission
	EQ7.5. Is the EU financing to the ESOs cost-efficient to support the international adoption of EU standards?	Union financing to ESOs is proportionate to the outputs related to the support of international adoption of EU standards.	➢ Cost/benefit ratio per activity aimed at international adoption of EU standards against existing alternatives.	○ Desk research on monitoring, reporting and guidelines: annual work programmes ► Interviews with ESOs ► Interviews with EU Commission
Relevance				
EQ8. To what extent have the objectives of the Regulation been relevant to address wider strategic needs of the European standardisation system explained in COM (2011) 311?	**EQ8.1.** To what extent have the objectives of the Regulation been instrumental to ensure the speed of the standards setting process?	The objectives and measures of the Regulation have been relevant to address the need of speeding up the standards setting process	➢ Number and list of factors making the objectives less relevant ranked by degree of relevance. ➢ Number and list of factors making the measures less relevant ranked by degree of relevance. ➢ Number and list of policy areas where speed of standardisation process still needs to improve.	○ Desk research on position papers (Industry associations, SBS). ► Public consultation ► Targeted survey of Industry associations ► Interviews with Industry associations ► Interviews with experts ► Interviews with ESOs
			➢	►
	EQ8.2. To what extent have the objectives of the Regulation been instrumental to address the problem of "Fora and Consortia Standards" not being referenced in	The objectives and measures of the Regulation have been relevant to enhance the referencing of	➢ Number and list of factors making the objective less relevant ranked by degree of relevance. ➢ Number and list of factors making the measures less relevant ranked by degree of relevance.	○ Database review of EC *eNorm Platform, European Commission standardisation requests* database. ○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs)

	public procurement of ICT?	standards in public procurement	➢ Number and list of policy and legislation areas where the contribution of standardisation process still needs to improve	► Public consultation ► Interviews with ESOs ► Interviews with the Commission
	EQ8.3. To what extent have the objectives of the Regulation contributed to ensure representation of SMEs and societal stakeholders in the standardisation process?	The objectives and measures of the Regulation have been relevant to address the need of increasing inclusiveness in the process	➢ Number and list of factors making the objective less relevant ranked by degree of relevance. ➢ Number and list of factors making the measures less relevant ranked by degree of relevance. ➢ Number and list of policy areas where social inclusiveness still needs to improve	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Desk research on position papers (Annex III organisations). ► Public consultation ► Interviews with ESOs ► Interviews with National Standardisation Bodies ► Targeted survey of Industry associations ► Targeted survey of Annex III organisations ► Interviews with Industry associations
EQ9. To what extent are the objectives of the Regulation still fit for purpose considering the new needs explained in the 2022 Standardisation COM (2022) 31 final	**EQ9.1.** To what extent is the current ESS including the public-private partnership, able to deliver on critical standardisation urgencies and policy priorities arising within the digital and green transformation of industries?	The objectives and measures of the Regulation are still relevant to address critical standardisation urgencies and policy priorities arising within the digital and green industries	➢ Share of stakeholders considering the objectives still relevant. ➢ Share of stakeholders considering the measures still relevant. ➢ Number and list of factors making the Regulation objectives less relevant to new emerging challenges.	○ Desk research on monitoring, reporting and guidelines: annual work programmes (ESOs) ► Public consultation ► Interviews with ESOs ► Interviews with National Standardisation Bodies ► Targeted survey of Industry associations ► Interviews with Industry associations ► Interviews with Annex III organisations

EQ9.2. To what extent is the current ESS still fit to the increased use of standards in the social area?	The objectives and measures of the Regulation are still relevant to address the increased use of standards in the social area	➢ Share of stakeholders considering the objectives still relevant. ➢ Share of stakeholders considering the measures still relevant. ➢ Number and list of factors making the Regulation objectives less relevant to new emerging challenges.	○ Desk research on position papers (ETUC, employers' associations). ○ Desk research on monitoring, reporting and guidelines: annual work programmes ► Public consultation ► Interviews with ESOs ► Targeted survey of ETUC, employers' associations ► Interviews with ETUC, employers 'associations
EQ9.3. To what extent is the current ESS still fit to preserve the integrity, inclusiveness, and accessibility of the system?	The objectives and measures of the Regulation are still relevant to address the need to preserve the integrity, inclusiveness, and accessibility of the system?	➢ Share of stakeholders considering the objectives still relevant. ➢ Share of stakeholders considering the measures still relevant. ➢ Number and list of factors making the Regulation objectives less relevant to new emerging challenges.	○ Desk research on position papers (Industry associations, Annex III organisations). ○ Desk research on monitoring, reporting and guidelines: annual work programmes ► Public consultation ► Interviews with ESOs ► Interviews with National Standardisation Bodies ► Targeted survey of Industry associations ► Targeted survey of Annex III organisations ► Interviews with Industry associations ► Interviews with Annex III organisations
EQ9.4. To what extent is the current ESS still fit to promote standard setting according to EU values at the global level	The objectives and measures of the Regulation are still relevant to address the need to promote standard setting according	➢ Share of stakeholders considering the objectives still relevant. ➢ Share of stakeholders considering the measures still relevant. ➢ Number and list of factors making the Regulation objectives less	○ Desk research on EU policy framework ○ Desk research on monitoring, reporting and guidelines: annual work programmes

	to EU values at the global level	relevant to new emerging challenges.	▶ Public consultation ▶ Interviews with ESOs ▶ Interviews with National Standardisation Bodies ▶ Targeted survey of Industry associations ▶ Interviews with Industry associations
EQ9.5. To what extent is the current ESS still fit to promote innovation and anticipate standardisation needs?	The objectives and measures of the Regulation are still relevant to address the need to foster innovation and anticipate standardisation needs	➢ Share of stakeholders considering the objectives still relevant. ➢ Share of stakeholders considering the measures still relevant. ➢ Number and list of factors making the Regulation objectives less relevant to new emerging challenges.	○ Desk research on position papers (Industry associations, SBS). ○ Desk research on monitoring, reporting and guidelines: annual work programmes ▶ Public consultation ▶ Interviews with ESOs ▶ Interviews with National Standardisation Bodies ▶ Targeted survey of Industry associations ▶ Targeted survey of Annex III organisations: SBS ▶ Interviews with Industry associations and SBS ▶ Interviews with experts
EQ9.6. To what extent is the current ESS still fit to ensure that the EU can count on skilled experts to deliver on policy and stakeholder needs?	The objectives and measures of the Regulation are still relevant to address the need of the EU to count on the appropriate experts to deliver on policy and stakeholder needs	➢ Share of stakeholders considering the objectives still relevant. ➢ Share of stakeholders considering the measures still relevant. ➢ Number and list of factors making the Regulation objectives less relevant to new emerging challenges.	○ Desk research on monitoring, reporting and guidelines: annual work programmes. ○ European Standardisation Panel ▶ Public consultation ▶ Interviews with ESOs ▶ Interview with National Standardisation Bodies ▶ Targeted survey with Industry associations ▶ Interviews with Industry associations

Coherence				
EQ10. To what extent is the Regulation 1025/2012 coherent with current EU policies, priorities, and terminologies, ensuring a unified approach within the EU legislative framework?	**EQ10.1.** Is the terminology between Regulation 1025/2012 and the GPSR coherent?	The terminology of the Regulation 1025/2012 is consistent with the GPSR	➢ Number of differences between regulation terminology and GPSR. ➢ Level of similarity between divergent terminology.	○ Interviews with DG JUST *Followed by* ○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Database review on EU institutions websites ○ Desk research: EU policy framework
	EQ10.2. Do the harmonised standards and technical specifications contribute to ensuring the success of the NLF?	The harmonised standards and technical specifications contribute to ensuring the success of the NLF.	➢ Number of (i) minimum market access conditions, (ii) some average market access conditions or (iii) top/demanding market access conditions of harmonised standards produced by ESOs.	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Database review on EU institutions websites ► Interviews with ESOs ► Interviews with the Commission
	EQ10.3. To what extent is the Regulation coherent with wider EU policies and priorities?	The Regulation is coherent with current wide EU priorities, especially in Single Market integration, environmental protection, digital innovation, and the related EU strategic autonomy aspects.	➢ Number of harmonised standards conflicting with EU policy priorities. ➢ Number of harmonised standard complementary with EU policy priorities. ➢	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Database review on EU institutions websites ○ Desk research: EU policy framework ► Interviews with the EU Commission ► Interviews with experts

	EQ10.4. Is the implementation of the Regulation coherent from one Member State to another?	The implementation of the Regulation is coherent across Member States.	➢ Number of national standards conflicting with harmonised standards. ➢ Number of overlapping procedures with the regulation at the Member State level. ➢ Number of transpositions of European standards into national standards	○ Desk research on monitoring, reporting and guidelines: annual work programmes, Report of the Commission to the Parliament & Council 2022 ○ Database review on NSBs websites ○ Desk research on position papers (Industry associations, SBS) ► Interviews with ESOs ► Targeted survey of National Standardisation Bodies ► Interviews with National Standardisation Bodies ► Targeted survey of Industry associations
EQ11. To what extent are the various elements of the Regulation 1025/2012 coherent internally with one another?	**EQ11.1.** Is the integrity during the standards development process and within the ESOs properly preserved in line EU interests and values?	Integrity with EU interests is maintained in the standards development process of ESOs.	➢ Number of standardisation goals in ESOs work programmes that diverge from standardisation strategy. ➢ Level of compliance of ESOs with principles of the WTO and European Standardisation System.	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Desk research on position papers (Industry associations, Annex III organisations) ○ Database review on EU institutions websites ► Interviews with ESOs ► Interviews with the EU Commission
	EQ11.2. Has any conflict between the provisions and measures of the Regulation emerged during the implementation?	There were no or minimal conflicts between provisions and measures of the Regulation that emerged during implementation.	➢ ➢ Number of conflicting provisions and measures. ➢ Stakeholders' perception on conflicting provisions and measures	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Database review on EU institutions websites ○ Desk research on position papers (Industry associations, Annex III organisations)

				○ Database: backlog of standards awaiting publication in the OJEU of the EU ► Interviews with ESOs ► Interviews with the EU Commission
EU added value				
EQ12. Is there additional value resulting from the Regulation, compared to what could be achieved merely at national level?		There is added value of EU intervention in this area.	➢ Magnitude and impacts of the non-delivery of harmonised standards. ➢ Number of non-citations in the OJEU and/or citations with a restriction.	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Database review on recent studies on standardisation
EQ13. To what extent do the issues addressed by the measure continue to require action at EU level?		The issues addressed by the Regulation continue to require action at the EU level as the consequences of stopping or withdrawing the measure would be negative	➢ Number of negative consequences on: (i) internal market, (ii) business competitiveness, (iii) consumers' safety, (iv) workers' protection and (v) environmental protection	○ Desk research on monitoring, reporting and guidelines: annual work programmes ○ Database review on recent studies on standardisation ► Interviews with ESOs ► Targeted surveys of National Standardisation Bodies ► Targeted survey of Industry Associations ► Interviews with Industry associations ► Targeted survey of Annex III organisations ► Interviews with Annex III organisations

ANNEX IV: OVERVIEW OF BENEFITS AND COSTS AND TABLE ON SIMPLIFICATION AND BURDEN REDUCTION

	Citizens/Consumers		Businesses		European Commission		ESOs		Annex III organisations		National Standardisation Bodies	
	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment
(1) Direct costs of regulation (annual recurrent costs)												
Direct compliance costs	-	-	-	-	Around €31,500,000	This includes all adjustment and administrative expenses as presented in section 4.2.1 of the study report.	Around € 530,000	Administrative costs for all ESOs	Around €277,000	Administrative costs for all Annex III organisations	Around €2,000,000	Administrative costs for all National Standardisation Bodies (NSBs/NCs/NSOs)
(2) Indirect costs of regulation (annual recurrent costs)												
Indirect compliance costs	-	-	Between € 64,800 and € 331,500	Interval of average participation costs in harmonised standards' revision and development for one standard for one business. No data available on the number of businesses participating	-	-	-	-	Between € 12,000 - € 83,000	Interval of average participation costs in harmonised standards' revision and development for one standard for one Annex III organisation	-	-

	Citizens/Consumers		Businesses		European Commission		ESOs		Annex III organisations		National Standardisation Bodies	
	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment
	-	-	€ 15 000 - € 500 000	Interval of costs of purchasing /subscribing to harmonised standards for one business	-	-	-	-	-	-	-	-

	Citizens/Consumers		Businesses		European Commission		ESOs		Annex III organisations		National Standardisation Bodies	
	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment	Estimate	Comment
(1) Direct regulatory benefits (annual recurrent benefits)												
Increase in welfare	Positive (qualitative score 2.75 / 5)	Increase in welfare of consumers	Slightly positive (qualitative score 1.1 / 5)	Direct economic benefits from participation in harmonised standards development. Not possible to quantify in monetary terms.	-	-	-	-	-	-	-	-
	Positive (qualitative score 3.5 / 5)	Increase in welfare of the environment	Slightly positive (qualitative score 1.8 / 5)	Direct economic benefits from using harmonised standards for conformity assessment. Not possible to quantify in monetary terms.	-	-	-	-	-	-	-	-
	Highly positive (qualitative score 4 / 5)	Increase in welfare of workers	-	-	-	-	-	-	-	-	-	-
(2) Indirect regulatory benefits (annual recurrent benefits)												
Wider macroeconomic benefits	-	-	Increase in trade	Not possible to quantify	-	-	-	-	-	-	-	-

TABLE ON SIMPLIFICATION AND BURDEN REDUCTION Part I: Simplification and burden reduction (savings already achieved) Report any simplification, burden reduction and cost savings achieved already by the intervention, including the points of comparison/baseline where available (e.g. REFIT savings predicted in the IA or other sources).									
	Cost according to EU Standard Cost Model	**Annex III organisations**		**Businesses**		**European Commission**		**European and national standardisation Bodies**	
		Quantitative	**Comment**	**Quantitative**	**Comment**	**Quantitative**	**Comment**	**Quantitative**	**Comment**
Direct compliance costs									
Recurrent	**Direct compliance costs generated by the impossibility to reference Fora and Consortia Standards in public procurement**					Some cost savings have emerged, but it is not possible to quantify them.	Regulation 1025/2012 has introduced a mechanism for referencing Fora and Consortia Standards in public procurement of ICT. Baseline: The legislation in force at the time of the Regulation did not include, in the list of standards to which public authorities are allowed to refer in their procurement		

Indirect costs									
Recurrent	**Indirect compliance costs generated by conflicting national standards**			Some cost savings have emerged, but it is not possible to quantify them.	Regulation 1025/2012 has improved the alignment of national and European standards at the request of the Commission. This has contributed to simplifying conformity assessments through the presumption of conformity granted by the use of harmonised standards and therefore decreasing technical barriers to trade. Baseline: persistence of conflicting national standards				

	Indirect compliance costs generated by limited coordination between European Standardisation Bodies and National Standardisation Bodies/National Committes/National Standardisation Organisations							Some cost savings have emerged, but it is not possible to quantify them.	The Regulation 1025/2012 has had an indirect effect on the simplification of coordination, leading to the increased use of ICT tools by ESOs and NSBs/NCs/NSOs for their coordination activities, although there remains significant scope for improvement.

Opportunity costs									
Recurrent	Opportunity costs deriving from long development times of standards			Some cost savings have emerged, but it is not possible to quantify them.	Regulation 1025/2012 has moderately improved the speed of standards' development at the request of the Commission. This has contributed to decreasing the opportunity costs of using other means of conformity assessments to placing products on the single market. However, legal and procedural developments influenced the overall functioning of the European standardisation system and added more administrative burden both within the technical committees of the European standardisation organisation and on the				

					European Commission.				

Part II: Potential simplification and burden reduction (savings)									
Identify further potential simplification and savings that could be achieved with a view to make the initiative more effective and efficient without prejudice to its policy objectives									
	Cost according to EU Standard Cost Model	**Annex III organisations**		**Businesses**		**European Commission**		**European and national standardisation Bodies**	
		Quantitative	**Comment**	**Quantitative**	**Comment**	**Quantitative**	**Comment**	**Quantitative**	**Comment**
Direct compliance costs									
	Direct compliance costs: costs of reporting	Potential cost savings have emerged, but it is not possible to quantify them.	Costs of reporting could be decreased by improving the reporting mechanism. The current monitoring system - limited to Art. 24 - is currently based on high-level templates to be filled in and submitted in the form of PDFs documents by ESOs and Annex III orgs. A more digitised/online system could make the reporting less costly while at the same time make the collected data more comparable.					Potential cost savings have emerged, but it is not possible to quantify them.	Costs of reporting could be decreased by improving the reporting mechanism. The current monitoring system - limited to Art. 24 - is currently based on high-level templates to be filled in and submitted in the form of PDFs documents by ESOs and Annex III orgs. A more digitised/online system could make the reporting less costly while at the same time make the collected data more comparable.
	Direct compliance costs: costs of standardisation requests					Potential cost savings have emerged, but it is not possible to	Streamlining standardisation requests negotiation between the Commission		

						quantify them.	and ESOs before starting the "official" issuance and acceptance process of one mandate (lasting one month) could help decrease time		
	Direct compliance costs: formal objections					Potential cost savings have emerged, but it is not possible to quantify them.	More streamlined and structured procedures form formal objections could reduce the costs linked to waiting time borne by the Commission and companies interested in the (h)ENs affected by one objection		
	Direct compliance costs: costs of monitoring the life-cycle of one standard					Potential cost savings have emerged, but it is not possible to quantify them.	A more streamlined monitoring mechanism for the entire "life-cycle" of one standard in all its phases, from standardisation request to harmonisation, could be established.		

Indirect compliance costs									
	Indirect compliance costs: participation in standardisation	For each day of expert participation less, an organisation could save EUR 600 per expert[234]. With an average of 22 working days per expert per year, a reduction of 25% of participation days would result in a saving of EUR 3 300 per expert.	If standardisation processes can be made faster and more efficient (e.g. through the increased use of digital technologies), expert participation costs can be reduced. This applies to all experts.	For each day of expert participation less, an organisation could save EUR 600 per expert. With an average of 22 working days per expert per year, a reduction of 25% of participation days, would result in a saving of EUR 3 300 per expert.	If standardisation processes can be made faster and more efficient (e.g. through the increased use of digital technologies), expert participation costs can be reduced.				
Opportunity costs									
	Opportunity costs: due to the delays in citation time		For each standard reducing by 50% unnecessary waiting time before harmonisation, one company could save on average around €3,700 per standard used for conformity assessments.	When EU businesses use harmonised standards, they benefit from the presumption of conformity which significantly decreases the compliance costs. When companies wait for the development and publications of harmonised standards, they may face some costs including those of using notified bodies for conformity assessments or waiting to place their products*.					

**Data on this opportunity cost are collected through targeted surveys of businesses using stated preference techniques (see Better Regulation Toolbox TOOL #57, Box 8), with a sample size of responses from 17 companies*

[234] Based on an average of EUR 600 per day per expert, see Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States", November 2021, European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. Section 4.1.3.3.1

ANNEX V: SYNOPSIS REPORT OF THE STAKEHOLDER CONSULTATION

Introduction

This document presents the synopsis report on the consultation activities held for the Evaluation Study of the Regulation (EU) No 1025/2012. The stakeholder consultation aimed at collecting evidence to evaluate the implementation and the performance of the Regulation, addressing the five evaluation criteria included in the Better Regulation Guidelines.

Consultation activities

The consultation activities were conducted between September 2023 and October 2024, including:

- A call for evidence was launched on the Have your say portal between 1 September 2023 and 29 September 2023.
- Ten scoping interviews between December 2023 and January 2024 to finalise the theoretical framework
- A call for evidence
- A public consultation open from 2 May to 25 July 2024
- Three targeted surveys open between July and August 2024
- Forty-six interviews between August and October 2024 to investigate specific topics in-depth and fill data gaps

The public consultation and the targeted surveys were conducted virtually, through the EU Survey Tool[235], and they were widely disseminated among stakeholders using different channels:

- The public consultation was published in the *Have your say* portal
- E-mails were sent to previously identified stakeholders both at the EU (umbrella organisation) and national levels

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

Overall, the consultation process engaged a broad and diverse range of relevant stakeholders, ensuring the inclusion of multiple perspectives on the Regulation. Key participants included representatives from the NSBs/ NCs/NSOs, all European Standardisation Organisations (ESOs), International Standardisation bodies (ISBs), as well as all Annex III organisations, trade and business associations, companies, industry experts, and research institutions. Notably, a significant portion of consulted industry stakeholders represent sectors covered by harmonised standards, ensuring that critical areas of industry were represented.

Table: Sectorial coverage in all consultations activities

Sectors by harmonised legislation	Consulted stakeholders
Accessibility of websites and mobile applications of public sector bodies	2% (n=1)
Chemical substances (REACH)	4% (n=2)
Community postal services	2% (n=1)

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

Sectors by harmonised legislation	Consulted stakeholders
Construction products (CPD/CPR)	17% (n=9)
Eco-design and energy labelling	13% (n=7)
Lifts	4% (n=2)
Low Voltage (LVD)	7% (n=4)
Machinery (MD)	13% (n=7)
Medical devices (Directive 93/42/EEC)	2% (n=1)
Medical devices (Regulation 2017/745)	2% (n=1)
New Legislative Framework (NLF) and Eco-Management and Audit Scheme (EMAS)	2% (n=1)
Personal protective equipment (PPE)	4% (n=2)
Radio Equipment (RED)	13% (n=7)
Rail system: interoperability	6% (n=3)
Recreational craft and personal watercraft	2% (n=1)
Unmanned aircraft systems (UAS)	2% (n=1)

Many of the consulted trade and business associations are umbrella organisations at the EU level, representing a wide network of companies of various sizes, from SMEs to large multinational corporations. This layered representation enhanced the relevance of the feedback, as these associations bring together businesses from diverse industries and countries.

While some gaps in stakeholder representation were identified, such as limited input from certain niche sectors or specific geographic areas, the overall diversity of the respondents ensures that the feedback provides a comprehensive and balanced understanding of the Regulation.

Call for evidence

A call for evidence was launched on the Have your say portal between 1 September 2023 and 29 September 2023. A total of **90 valid feedback** was received covering various EU countries, including Belgium (37%, n=33), France (10%, n=9), Germany (10%, n=9), Sweden (6%, n=5) and Italy (6%, n=5).

The table below summarised the stakeholder category of respondents:

Table: Responses to the call for evidence by stakeholder group

Sectors	Feedback received
Business associations	34
Non-Governmental organisations	12
Company/Business	10
EU citizens	10
Public Authority	7
Consumer Organisation	2
Academic/research institutions	2
Environmental organisations	1
Trade unions	1
Other	11

Responses to the Call for Evidence (CfE) indicate both its achievements and areas for improvement. While most stakeholders indicate that the Regulation has increased inclusiveness, especially for SMEs and societal stakeholders, challenges persist. Industry and civil society alike cite delays in standardisation processes, slow adoption of harmonised standards as concerns. Societal stakeholders call for enhanced funding and support for smaller civil society organisations. Most stakeholders indicate that there is a need for improvements in implementation—particularly regarding HAS consultants. Despite these issues, the majority of stakeholders see the Regulation as largely fit for purpose, though refinements are deemed necessary.

Responses reveal varied experiences with ICT standards in public procurement. Industry stakeholders and public authorities indicated that the Regulation initially enhanced efficiency by aiding the identification of technical specifications, yet progress has stagnated since 2019. Concerns about slow processes, difficulties in aligning with global standards, and limited recognition of open-source technologies were frequently raised. Practical improvements are essential to maintain relevance and competitiveness on a global scale.

All stakeholder groups cite delays in developing harmonised standards as a recurring issue, driven by lengthy administrative processes, inconsistent HAS consultant involvement, and slow citation in the Official Journal. In particular, industry stakeholders emphasise that these delays hinder innovation and create obstacles for fast-moving sectors like ICT. Industry and societal stakeholders suggest earlier involvement from the European Commission and national authorities to streamline processes.

Industry stakeholders shared concerns on the competitiveness of harmonised standards, which can diverge from international market trends, and be slow to update. Industry stakeholders emphasise that this creates barriers for European companies, particularly SMEs, in global markets. Inefficiencies in the system, such as costly access to standards, lack of transparency, and underrepresentation of certain stakeholders, exacerbate these challenges. Industry stakeholders indicate that the ESS faces difficulties expanding into emerging technical areas due to licensing issues, inconsistent participation from public authorities, limited industry interest, and resource constraints.

Industry stakeholders call for greater alignment with international standards is viewed as essential to minimise trade barriers and enhance global competitiveness. To strengthen participation, societal stakeholders and SMEs suggest improving transparency, reducing costs of access, and providing more support for SMEs and underrepresented groups, such as civil society and academic researchers.

Public Consultation

The public consultation received 253 valid replies that were submitted[236]. Specifically, 63 respondents (25%) were from business associations, while 58 respondents (23%) represented companies or businesses. Other notable groups included respondents

[236]The total number of replies submitted amount at 255, but 2 replies were identified as duplicates, and they were removed from the analysis

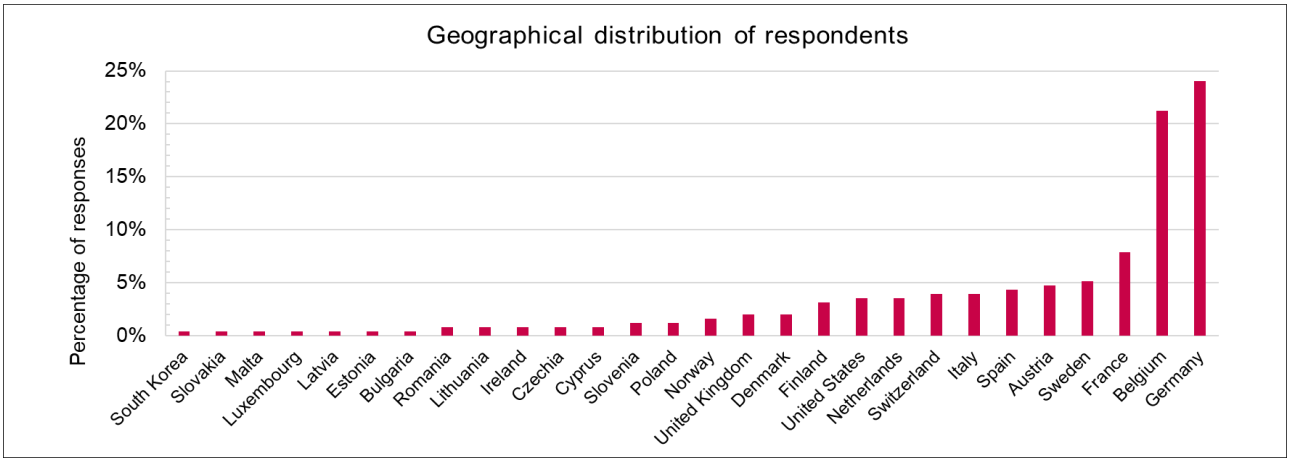
categorised as "Other" (29 respondents, 11%), public authorities (27 respondents, 11%), and non-governmental organisations (NGOs) with 24 respondents (10%).

EU citizens contributed with 17 responses (7%), while trade unions accounted for 14 responses (6%). Smaller groups included academic or research institutions (9 respondents, 4%), consumer organisations (8 respondents, 3%), non-EU citizens (3 respondents, 1%), and environmental organisations, with just one respondent.

Most importantly, it should be noted that key actors of the Regulation at the European level all contributed to the public consultation, including the three ESOs[237] and the four Annex III organisations. Also, participation of national actors was high, with 28 NSBs represented from 21 different countries.[238]

The largest proportion of respondents came from Germany, contributing 61 **responses (24% of the total). Belgium also had a significant representation with 54 respondents (21%).** Other notable contributions came from France with 20 respondents (8%), Sweden with 13 respondents (5%), and Austria with 12 respondents (5%).

Figure 0.1.Graphical distribution of PC respondents



Targeted surveys

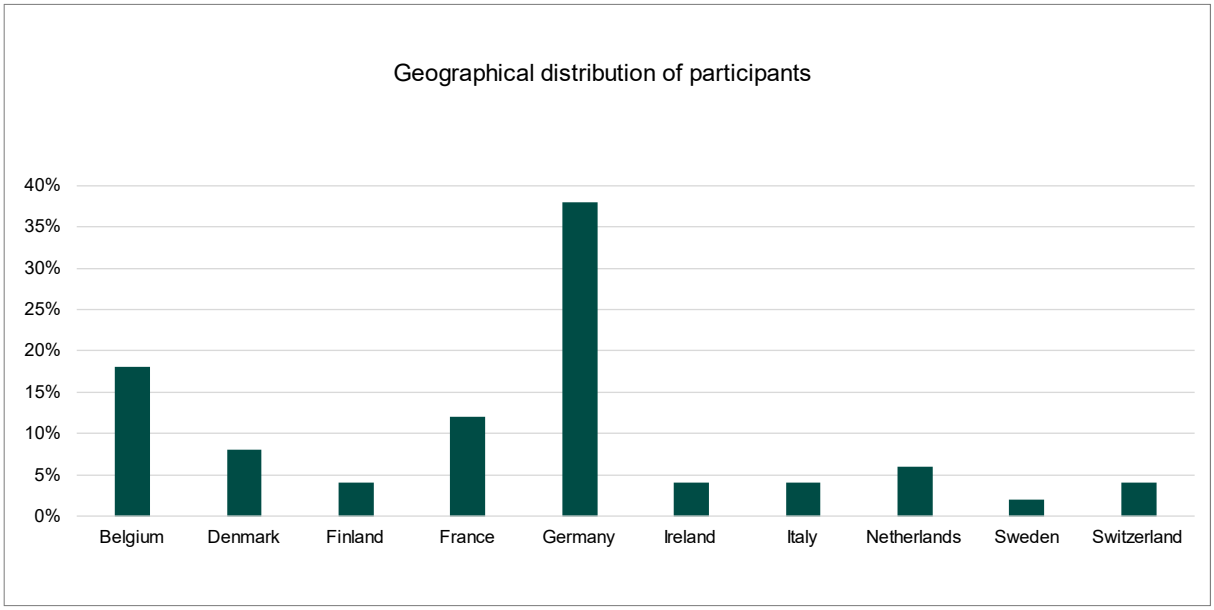
Industry

A total of **50 responses** were received in the industry and companies survey, including one submission from the Annex III organisation SBS-Small Business Standards. The responses represented a diverse range of countries, including Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Sweden, and Switzerland. The distribution of responses across these countries varied: Germany accounted for the highest proportion, with 38% of the total responses, followed by Belgium and France, which contributed 18% and 12%, respectively. The remaining countries each contributed between 8% and 2% of the total responses.

[237] CEN and CENELEC provided a joint reply

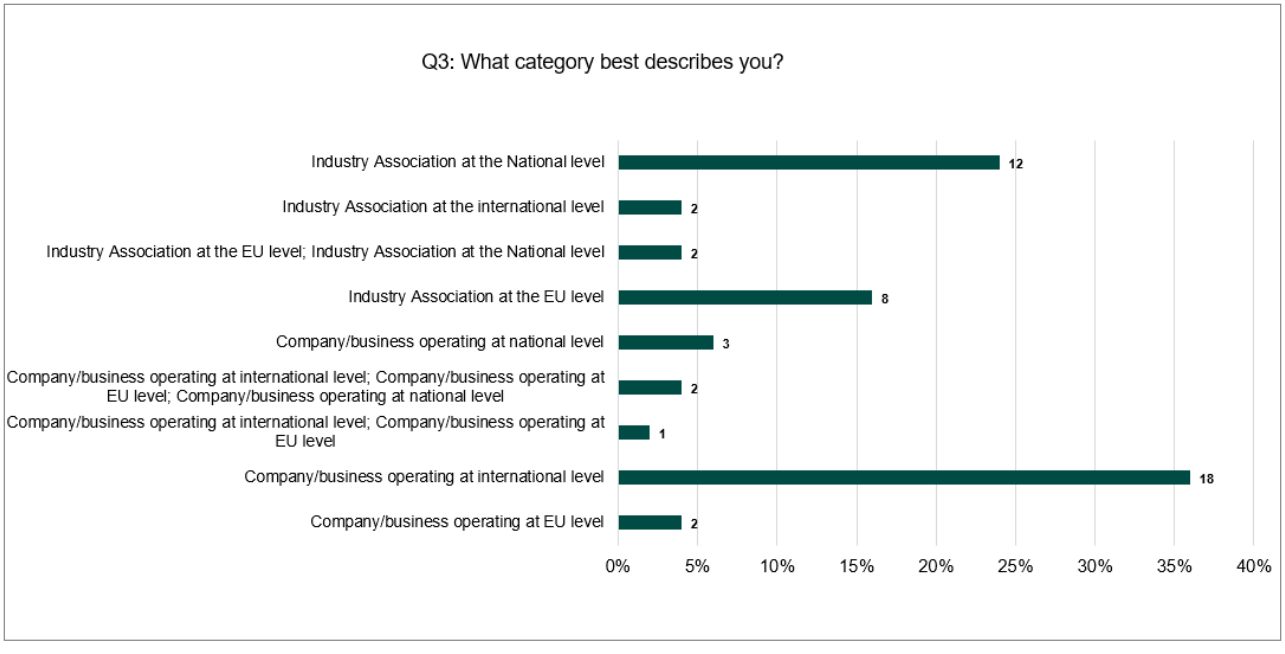
[238] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Romania, Slovakia, Spain, Sweden

Figure 0.2. Geographical distribution of Industry TS respondents



Among the submitted responses, **52% were from companies/businesses**, with the following distribution of operational scope: 4% operate at the EU level, 6% at the national level, 36% at the international level, 2% at both the international and EU levels, and 4% operate across the EU, international, and national levels. **48% of the responses came from this industry associations**. Of these, 16% operate at the EU level, 24% at the national level, 4% at the international level, and 4% operate at both the national and EU levels

Figure 0.3 Categories of respondents to Industry TS



National Standardisation Bodies

A total of 22 NSBs from across the European Union participated in the survey, representing a diverse range of countries. These include Austria, Cyprus, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, the Netherlands, Portugal, Bulgaria, Romania, Slovakia, Spain, and Sweden.

Annex III organisations

All the Annex III organisations provided their responses through the targeted survey.

Interviews

The table below summarises the interviews conducted by stakeholder groups:

Table: Interviews conducted by stakeholder group

Stakeholder category	N. of interviews in the scoping phase	N. of interviews in the data collection phase
European Commission (GROW, JUST, CNECT and JRC)	1	3
International Standardisation Bodies	-	1
European Standardisation Organisations (ESOs)	3	2*
Annex III organisations	4	4
National authorities	-	2
NSBs / NCs / NSOs	-	1
HAS Consultants	-	1
National Accreditation Body	-	1
National consumer association	-	1
Trade and business associations	1	16
Companies / Businesses	1	10
Academia, Research Institute and Think Tanks	-	4
Total	**10**	**46**

**CEN and CENELEC were interviewed together*

Main results of consultations

EQ1. To what extent has the Regulation 1025/2012 achieved its objectives related to the standardisation process in enhancing the speed of European standards setting processes?

The consultations gathered relevant data on the speed of the European standards setting process, focusing on two key aspects:

- The time needed to develop and publish a harmonised standard in the OJEU following the adoption of standardisation request procedures (Article 10).
- The way the current governance of the European Standardisation System is perceived (either as an accelerator or a factor slowing down the standardisation process).

In the public consultation, when asked about the extent to which the Regulation achieved its general objectives, specifically for reducing the time taken by the

standardisation process,[239] 20% of respondents reported this was achieved to a large extent, 20% to a moderate extent, 25% to a small extent, and 19% not at all.

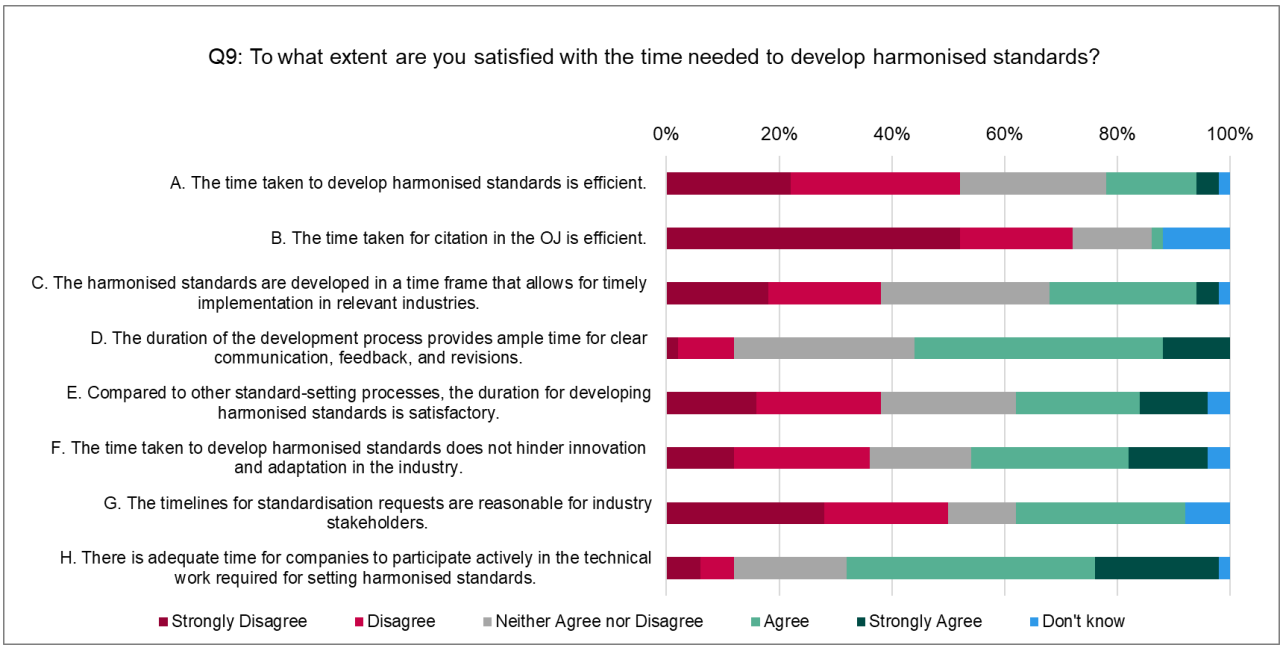
The results from the targeted survey for industry stakeholders suggested that they are generally not satisfied with the timeframes involved in both the development and citation of harmonised standards.[240] This feedback is shared across organisations of different sizes, with SMEs expressing concerns similar to those of large companies regarding the timeframe of the standardisation process.

- **Time to develop harmonised standards**: When asked about the efficiency of the time taken to develop harmonised standards, only a small percentage (4% strongly agree, 16% agree) considered the current process efficient. The remaining answers varied: 22% strongly disagreed, 30% disagreed, 26% neither agreed nor disagreed and 2% reported they 'Don't know'.
- **Time to cite harmonised standards**: A larger proportion of respondents (52%) strongly disagreed with the efficiency of the timeliness of citation in the OJEU, indicating a strong dissatisfaction, while 20% disagreed, 14% neither agreed nor disagreed, 2% agreed and 12% selected don't know as an answer.
- **Time for industry implementation**: Similarly, the timeliness of standards development for industry implementation was considered inadequate by 20% (disagree) and 18% (strongly disagree) of respondents, although 26% did agree the process was timely, while 30% were neutral.
- **Time for communication and feedback**: In contrast, the majority of respondents provided positive feedback regarding the time for communication and feedback, with 44% agreed, 12% strongly agreed, while 10% disagreed and 2%strongly disagreed.
- **Comparison with other standard setting processes**: When comparing this process with other standard-setting processes, 12% strongly agreed and 22% agreed that the duration is satisfactory, while the same percentage 22% disagree, and 16% strongly disagree.
- **Relationship with innovation**: Industry stakeholders provided with similar responses regarding whether the time of the process does not hinder innovation, with 28 % agreed, 14% strongly agreed, while 24% disagreed and 12% strongly disagreed.
- **Reasonableness of timeframes**: Most industry stakeholders reported that the time of the process is not reasonable for their industry, with 26% agreed, 4% strongly agreed, while 20% disagreed and 18% strongly disagreed.
- **Time to participate in technical discussions**: In contrast, the majority of respondents provided positive feedback regarding the timing being adequate for companies to actively participate in the technical work required for setting

[239] Public Consultation Q9: To what extent has the Regulation (EU) 1025/2012 achieved its general objectives? Sample size: N = 254
[240] Targeted Survey Industry Q9: To what extent are you satisfied with the time needed to develop harmonised standards? Sample size: N = 50

harmonised standards. Specifically, 22% strongly agreed, and 44% agreed. At the same time, 20% gave neutral feedback, 2% indicated they did not know, 6% disagreed, and 6% strongly disagreed.

Figure 0.4 Industry and companies views on the time needed to develop harmonised standards



The targeted surveys of industry stakeholders, Annex III organisation and National Standardisation Bodies collected views on the effectiveness of recent initiatives aimed at further reducing the time needed to develop harmonised standards:

- **Industry associations and companies**: Mixed opinions were noted. Improvements in ICT tools used by European and National Standardisation Bodies were widely viewed as the most effective, with 50% and 46% agreeing and 12% (for both options) strongly agreeing that these initiatives have contributed to further reducing the time needed to develop harmonised standards[241]. The establishment of a Task Force on Timely Delivery also received moderate support, with 30% agreeing and 6% strongly agreeing. However, initiatives like the establishment of HAS Consultants was less positively received[242]. A significant 44% strongly disagreed with the initiative on the establishment of the HAS Consultants to improve the quality of the deliverables. On the other hand, only 28% agreed with the initiatives to facilitate SME access to standardisation[243]. Article 10 of Regulation (EU) No 1025/2012 also received mixed feedback, with 34% agreeing or strongly agreeing about its effectiveness and 20% disagreeing or strongly disagreeing[244].

[241] Targeted Survey Industry Q12: To what extent do you believe that the following recent initiatives have contributed to further reducing the time needed to develop harmonised standards? Sample size: N = 50
[242] Ibid.
[243] Ibid.
[244] Ibid.

- **Annex III organisations:** In general, respondents indicated positive views on the recent initiatives.[245] Most respondents neither agreed nor disagreed that HAS Consultants (75%,) have contributed to reducing the time needed.[246] In contrast, half of the respondents (50%) were unsure about whether the amendment to Article 10 of Regulation contributed to reducing the time needed to develop harmonised standards.[247] Similarly, most respondents (75%) indicated that they neither agree nor agree that deadline for development of harmonised standards contributed to reducing the time needed to develop harmonised standard. [248]

  Conversely, the majority of respondents agreed (75%) that task force on timely delivery contributed positively. [249] Similarly, respondents generally agreed (75%) that Improvements in ICT Tools Used by ESOs have positively impacted the development process. Finally, half of the respondents agreed that dissemination and learning activities conducted by ESOs and NSBs (50%) contributed to reducing the time needed to develop harmonised standards[250].

- **National standardisation Bodies**: The responses indicated mixed opinions, with a notable proportion of respondents neither agreeing nor disagreeing with the effectiveness of these initiatives.[251] Exceptionally with regard to the establishment of the task force on timely delivery between EC, ESOs and EFTA, the majority of respondents strongly agreed (50%) and agreed (41%) that the initiative contributed to further reduce the time needed to develop harmonised standards[252].

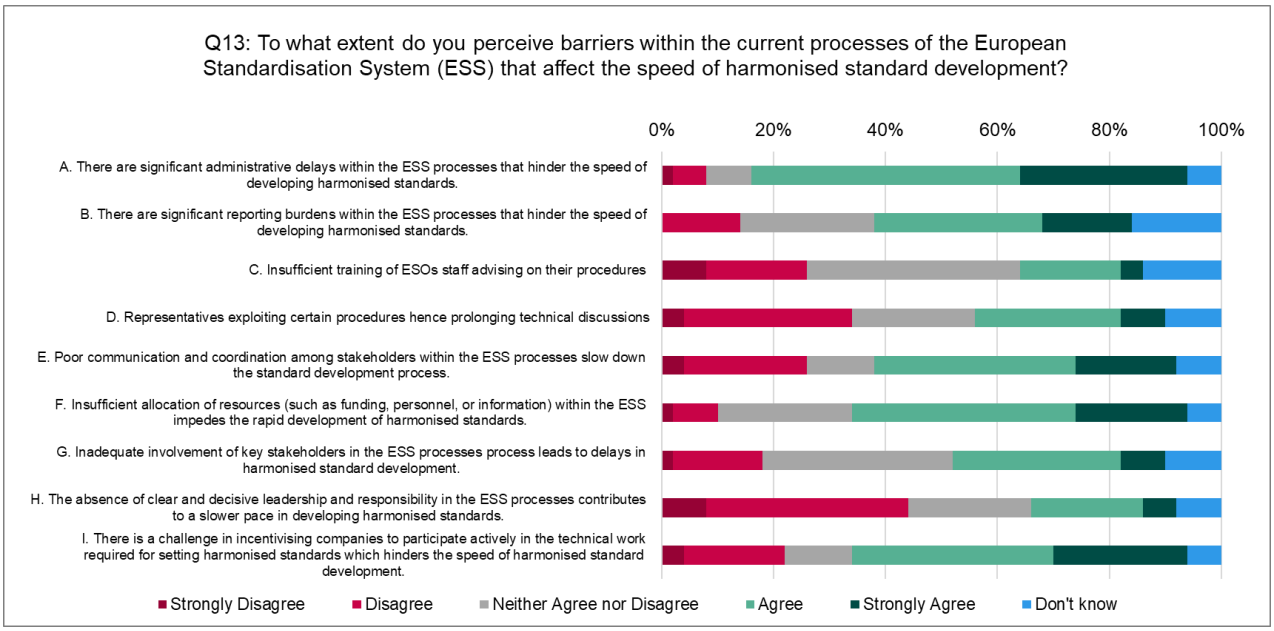
The targeted survey for industry associations and businesses also gathered data related to the perceived barriers within the European Standardisation System (ESS) that may impact the speed of harmonised standard development[253].

A significant number of industry stakeholders (48%) agreed, and 30% strongly agreed, that administrative delays within the ESS processes are a major barrier to the timely development of standards. Similarly, 30% of respondents agreed and 16% strongly agreed that the reporting burdens within the ESS also hinder progress, though a notable 14% disagreed. Poor communication and coordination among stakeholders is another cited barrier, with 36% agreeing and 18% strongly agreeing that this slows down the process. Resource allocation, particularly insufficient funding, personnel, or information was highlighted by 40% of respondents as a key obstacle, with 20% strongly agreeing. Furthermore, 30% of respondents agreed that inadequate involvement of key stakeholders in the ESS processes contributes to delays, with 8% strongly agreeing. Regarding the absence of clear leadership and responsibility within the ESS 36% disagreed and 6%

[245] Targeted Survey Annex III organisations Q5: To what extent do you believe that the following recent initiatives have contributed to further reducing the time needed to develop harmonised standards? Sample size: N=4
[246] Ibid.
[247] Ibid.
[248] Ibid.
[249] Ibid.
[250] Ibid.
[251] Targeted Survey National Standardisation Bodies Q7: To what extent do you believe that the following recent initiatives have contributed to further reducing the time needed to develop harmonised standards? Sample size: N = 22
[252] Ibid.
[253] Targeted Survey Industry Q13: To what extent do you perceive barriers within the current processes of the European Standardisation System (ESS) that affect the speed of harmonised standard development? Sample size: N = 50.

strongly disagreed. Finally, the challenge of incentivising companies to participate actively in technical work was another significant barrier, with 36% agreeing and 24% strongly agreeing.

Figure 0.5 Industry and companies views on the barriers affecting the speed of harmonised standard development (N=50)



Three key themes have emerged during the interviews with industry stakeholders, Annex III organisations, European Standardisation Organisations and one national consumer association, regarding the speed of the harmonised standards development process:

- **The speed of development and citation appears to vary by harmonised standards**. Some interviews with industry stakeholders and Annex III organisations suggested that speed appears to have increased for some harmonised standards without limiting the time needed for the consensus-building process. In other cases, other interviews with industry stakeholders and Annex III organisations suggested there has not been enough time for adequate discussion due to shorter timelines generated by cases when deadlines for standardisation requests did not adequately consider the time for consensus building process.
- **Some interviews with industry stakeholders suggested that the speed of development and citation is not in line with market needs.** These interviews indicated that market needs are evolving at a faster rate than harmonised standard development. Interviewees have expressed most concerns on the impact of the current speed of the system on industries that are experiencing significant emerging innovation, such as ICT, energy and utilities as well as services.
- **Other interviews with industry stakeholders, Annex III organisations, and one national consumer organisation indicated that the time for citation in the OJ has increased disproportionately compared to the reduction in time of development**. These interviews indicated that due to increasing waiting times for

citation, businesses face some challenges in marketing and producing goods and services when outdated standards are cited in the OJ. Official statistics show that while development time is absolute terms longer than citation time, the latter has increased at a higher rate than the former[254].

With regards to the actors in the process, two main themes have emerged from the **interviews with industry associations and companies, Annex III organisations, European Standardisation Organisations and one national consumer association** show that **HAS consultants' work is still perceived as a barrier:**

- **On one hand this depends on a case-by-case basis**, where some obstacle have emerged: (i) some interviews suggested that HAS consultants have not followed a uniform approach in their revision, (ii) other interviews highlighted that some comments from consultants could have been avoided if they were engaged earlier in TCs/WGs, and that this issue is further increased by the anonymity of HAS consultants (perceived from industry as a lack of transparency in the process).
- On the other hand, one interview with a well-experienced HAS consultant, confirmed that one of the main drivers behind these perceived issues is **a general lack of awareness**: (i) industry experts participating in TCs/WGs are not always fully aware of what HAS consultants are supposed to do (i.e. supporting the Commission in assessing compliance with legislation served by the EN which needs to be harmonised), but at the same time (ii) the pool of HAS consultants is a pool of different experts who can provide differing performance (in this regard consultants have an internal peer-review system to evaluate the performance of HAS consultant, e.g. quality of feedback given, respect of deadlines etc.) and that it could be that some HAS need trainings to fully perform their role more than others.
- Finally, both the industry representatives consulted and the HAS consultant acknowledged that **budgetary constraints** may have been another driver behind industry complaints about the work of HAS consultants. For example, between the end of the first Framework Contract (FwC) for HAS consultants (2018-2022) and the effective starting of the HAS' work (2018-2022) under the new FwC, several months passed without HAS being operative. This created a backlog of ENs waiting for harmonisation. While this seems a purely administrative reason, it reflects also possible reasons behind the complaints of the industry: (i) the backlog created frustration in industry representatives waiting for harmonisation, (ii) the anonymisation was introduced in order to avoid breaking the budget ceiling of FwC; when HAS consultants were not anonymised they could be directly engaged in TCs/WGs during the technical work (which, as stated above, is appreciated by industry experts) but all the high costs of participation were covered under the FwC.

EQ2. To what extent has the Regulation 1025/2012 achieved its objectives in enhancing stakeholder participation in European Standardisation?

[254] For more details, please consult Chapter 3, section 3.1.4.

The consultations collected data on several dimensions of stakeholders' participation in the European Standardisation System:

- Level of participation in technical discussions, submitting comments on drafts, revising existing standards at the National Standardisation Bodies and European Standardisation Organisations level.
- Level of accessibility and clarity of National Standardisation Bodies' and European Standardisation Organisations' work programmes and of the EU Annual Union Work Programmes.
- Level of acceptance of harmonised standards by businesses.

The public consultation results revealed varied perceptions regarding the effectiveness of the Regulation in engaging different stakeholder groups[255]. For the participating **SMEs and startups**, 22% of respondents strongly agreed that the Regulation has ensured their engagement and effective participation, and 27% agreed. In contrast, 17% disagreed, and 5% strongly disagreed. For **societal stakeholders** 22% of respondents strongly agreed and 31% agreed. A further 19% were neutral, and 11% expressed uncertainty by choosing "I don't know." For the **research/academia community**, 19% respondents strongly agreed and 25% agreed on the effectiveness of the Regulation in ensuring their effective involvement. Conversely, 21% neither agreed nor disagreed. For **Member States' public authorities'** engagement, 20% strongly agreed, and 27% agreed, with 15% disagreeing or strongly disagreeing (4%).

Responses from the targeted surveys with industry stakeholders indicated that most industry stakeholders participate actively in the work of NSBs/NCs and ESOs. A significant portion of respondents (55%) strongly agreed that they actively participate in the technical discussions of standardisation at NSBs/NCs level, including drafting standards, submitting comments on drafts (55%), and revising existing standards (55%)[256]. While in ESOs, organisations strongly agreed that they are heavily involved in proposing new work items (54%), revising standards (56%), and disseminating adopted standards (58%)[257].

[255] Public Consultation Q21: To what extent do you believe that the Regulation (EU) 1025/2012 ensured the engagement and effective participation of the following stakeholders? Sample size, N = 254

[256] Targeted Survey Industry Q14: […] To what extent do you agree with the following statements about your organisation's overall participation in the work of National Standardisation Bodies (NSBs) /National Committees (NCs)? Please rate your level of agreement with the following statements. Sample size: N = 49, Note that although the question is mandatory, one response is missing as one respondent submitted their answer via e-mail and did not fill-in this question.

[257] Targeted Survey Industry Q19: To what extent do you agree with the following statements about your organisation's overall participation in the work of European Standardisation Organisations (ESOs)? Please rate your level of agreement with the following statements. Sample size: N = 49, Note that although the question is mandatory, one response is missing as one respondent submitted their answer via e-mail and did not fill-in this question.

Figure 0.6 Industry and companies views on their involvement in the work of NSBs/NCs (N=49)

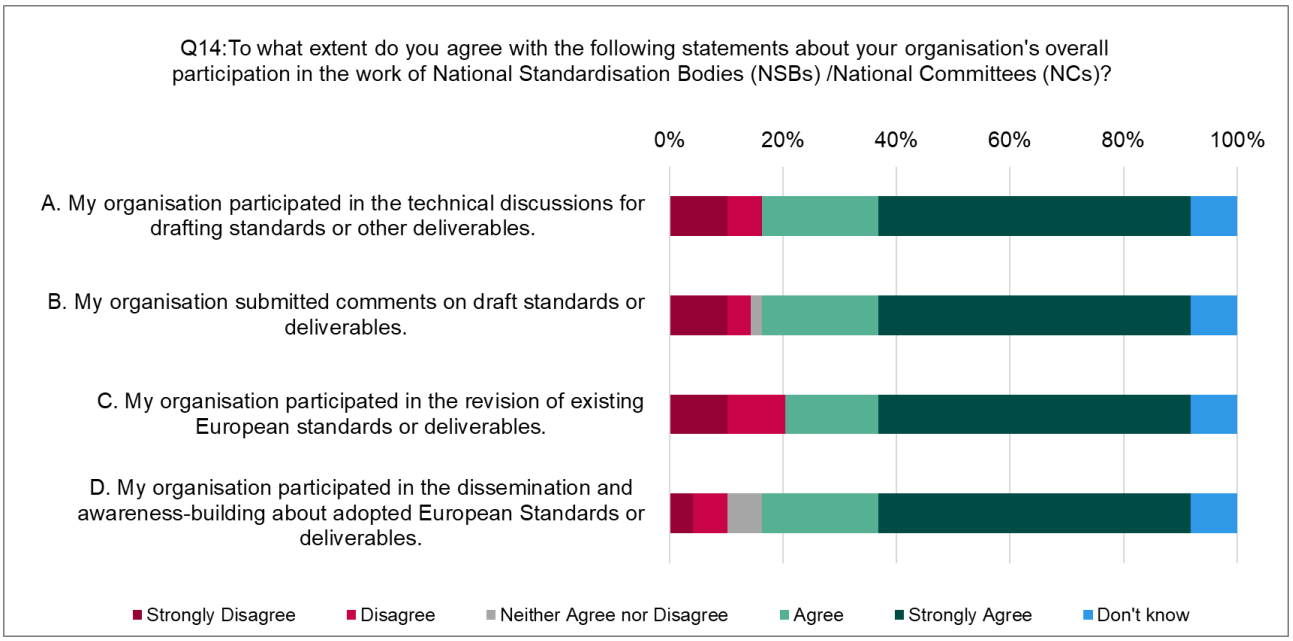
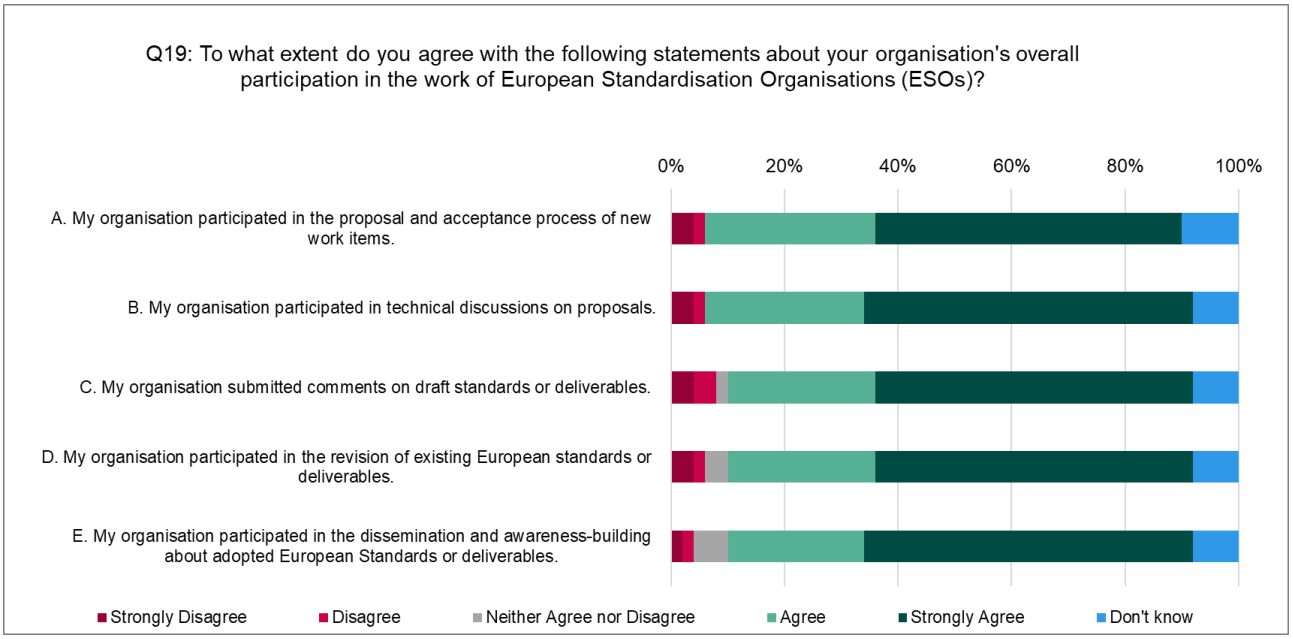


Figure 0.7 Industry and companies views on their involvement in the work of ESOs (N=49)



The targeted survey with industry stakeholders indicated that most of them see tangible benefits from their participation in standardisation work in both NSBs and ESOs:

- At the national level, most industry stakeholders indicated that they agree (29%) or strongly agree (47%) that participation allows them to influence sector-specific standards and represent their interests (29% agree, 47% strongly agree). Similarly, 20% agree and 57% strongly agree that participation gives them the opportunity to

contribute their expertise. Finally, 18% agree and 49% strongly agree that participation helps to shape the development of standards[258].

- At the European level, 46% of industry stakeholders agreed and 36% strongly agreed that participation lets them influence standards and represent their interests. Likewise, 26% agreed and 54% strongly agreed that it allows them to share their expertise. Lastly, 24% agree and 50% strongly agreed that their participation shapes standards development[259].

- In contrast, most industry stakeholders did not find that the participation at the national (4% disagreed, 22% strongly disagreed) and European level (20% strongly disagreed) result in strong representation at the political level. **Yet the results of the survey with industry stakeholders indicated that they are uncertain about whether the goal to enhance SMEs participation in NSBs and NCs has been met**.[260] When it comes to giving SMEs access to standardisation activities without requiring membership and providing free access or special rates for participation, most respondents rated the achievement as "Moderate" (26% and 37% respectively). Similarly, making abstracts of standards available for free and offering special rates or bundles of standards saw moderate ratings (26% and 32%). For making abstracts of standards available for free, it is notable to say that 26% reported “Very High” rating. **Responses from the targeted survey of Annex III organisations suggested that they are highly involved in the work of ESOs.** Half of the Annex III organisations strongly agreed that ESOs involve them in the proposal and acceptance of new work items, while the remaining half indicated that they agree**.** When it came to technical discussions on proposals, a three strongly agreed on their importance. Similarly, three strongly agree on the necessity of submitting comments on draft standards, the revision of existing standards, and the activities related to dissemination and awareness-building. Annex III organisations indicated that their level of participation varying across types of standards, being higher for standards triggered by mandates, followed by standards for products and finally standards for services[261]. **The majority of respondents to the targeted survey of National Standardisation Bodies (68%, n=15) indicated that public authorities, including market surveillance authorities are involved largely in national standardisation activities in their respective countries, while 27%**

[258] Targeted Survey Industry Q16: To what extent do you agree with the following statements about the benefits to your organisation of participating in the work of National Standardisation Bodies (NSBs) /National Committees (NCs)? Please rate your level of agreement with the following statements.) Sample size = 50

[259] Targeted Survey Industry Q21: To what extent do you agree with the following statements about the benefits to your organisation of participating in the work of European Standardisation Organisations (ESOs)? Please rate your level of agreement with the following statements. Sample size = 50

[260] Targeted Survey Industry Q18: Using a scale from 1 to 5, where 1 means ‘Very Low’ and 5 means ‘Very High’, how would you assess the degree of achievement of these objectives of SMEs involvement in National Standardisation Bodies (NSBs) /National Committees (NCs)? Please rate the level of achievement of the following objectives.
Sample size: N = 50.

[261] Targeted Survey Annex III organisations Q6: To what extent do you agree with the following statements about your organisation's overall participation in the work of European Standardisation Organisations (ESOs)? Sample size: N=4.

(n=6) of respondents only to a small extent[262]. This suggests that some differences exist in the participation of public authorities across Member States.

Additionally, the targeted surveys of industry stakeholders and Annex II organisations collected their views on the accessibility and clarity of the work programmes of the European Standardisation Organisations (ESOs), National Standardisation Bodies and Committees (NSBs/NCs), and the European Commission's Annual Union Work Programme (AUWP).

- **ESOs work programmes**: Most industry stakeholders indicated that the ESOs work programmes are generally accessible (28% agree, 20% strongly agree, 12% disagree, 16% neither agree nor disagree and 24% don't know), clear (40% agree, 10% strongly agree, 12% disagree, 14% neither agree nor disagree and 24% don't know), and relevant for the organisation objectives (30% agree, 12% strongly agree, 8% disagree, 24% neither agree nor disagree and 26% don't know). Industry stakeholders indicated that they effectively identify specific standards to be prepared or amended (28% agree, 10% strongly agree, 8% disagree, 26% neither agree nor disagree and 28% don't know), being prepared or amended (26% agree, 12% strongly agree, 10% disagree, 24% neither agree nor disagree and 28% don't know), have been adopted in the previous period (22% agree, 12% strongly agree, 10% disagree, 24% neither agree nor disagree and 32% don't know). Similarly, all Annex III organisations indicated that ESOs work programmes accessible, clear, and useful for their organisational objectives, but half indicate that they fail to identify specific standards being prepared, amended, or adopted[263].
- **NSBs/NCs' work programmes**: 40% of industry stakeholders indicated that NSBs/NCs' work programmes are accessible (24% agree, 16% strongly agree, 8% disagree, 20% neither agree nor disagree and 28% don't know), clear (34% agree, 12% strongly agree, 8% disagree, 14% neither agree nor disagree and 28% don't know) and relevant to organisational objectives (22% agree, 16% strongly agree, 8% disagree, 22% neither agree nor disagree and 30% don't know). Industry stakeholders indicated that they effectively identify specific standards being prepared (28% agree, 14% strongly agree), amended (28% agree, 16% strongly agree), or adopted (26% agree, 16% strongly agree). All Annex III organisations find that they could clearly identify the standards adopted in the previous period from work programmes[264].
- **Annual Union Work Programmes**: While some industry stakeholders indicated that they agree that the EU Annual Union Work Programmes (AUWP) identifies

[262] Targeted Survey National Standardisation Bodies Q5: Article 7 of the Regulation asks Member States to "encourage participation of public authorities, including market surveillance authorities, in national standardisation activities aimed at the development or revision of standards requested by the Commission in accordance with Article 10". To what extent is this Article implemented in your country? Sample size: N=22

[263] Targeted Survey Annex III organisations Q15, Targeted Survey Industry Q29: To what extent do you agree with the following statements about the transparency and quality of European Standardisation Bodies (ESOs) annual work programmes?
Targeted Survey Annex III organisations sample size: N = 4, Targeted Survey Industry sample size: N = 50.

[264] Targeted Survey Annex III organisations Q14, Targeted Survey Industry Q28: To what extent do you agree with the following statements about the transparency and quality of National Standardisation Bodies (NSBs)/National Committees (NCs) annual work programmes?
Targeted Survey Annex III organisations sample size: N = 4, Targeted Survey Industry sample size: N = 50.

EU strategic priorities for European standardisation (28%) a significant portion expressed doubts (16%) or did not know (30%). Similarly, several industry stakeholders agreed that AUWP identifies the specific objectives for standard development (32%), but 14% were uncertain and 32% did not know. Finally, most industry stakeholders (36%) indicated that they did not know whether from the AUWP they can identify urgent requests, and specific standards planned for development or amendment[265]. Overall, this shows low awareness of the content of the AUWP.

In addition, the targeted survey with industry stakeholders collected data the level of acceptance of harmonised standards, including adoption, implementation and adherence[266]. Industry stakeholders reported a high level of acceptance for harmonised standards with the majority rating them as widely accepted across all three categories: adoption (72%), implementation (68%), and adherence (62%)[267].

Finally, there are several themes that have emerged from the interviews with industry associations and companies, Annex III organisations, the research and academic community, national authorities, one disability experts and one national consumer association:

- **SMEs and startups**: In general, interviews with industry associations, companies and Small Business Standards (SBS) indicate that the representation of SMEs has improved under the Regulation. However, some companies report that they saw no improvement. With regards to startups, some research and academic stakeholders reported that the representation of startups is still low. Interviewees from industry associations, companies, SBS and research and academic stakeholders agree that there are two barriers to participation for SMEs and startups. The first barrier is the lack of resources to participate effectively, while the second barrier is the lack of expertise in standards. At the national level, interviews indicated that in general National Standardisation Bodies have implemented effective measures to engage SMEs in participation to standardisation activities. While the majority of industry stakeholders perceive that the representation of SMEs is crucial to standardisation, one company stated that the participation of large companies is enough to represent wider economic interests including those of SMEs and startups.
- **Annex III organisations**: Interviews with Annex III organisations revealed that their participation in European standardisation activities has increased under the Regulation. In particular, ANEC has stated that without Union Financing they would struggle to effectively represent consumers' interests in standardisation. However, Annex III organisations agree that there are some areas of improvement. First, challenges persist in their representation at the international level. This is due

[265] Targeted Survey Industry Q30: To what extent do you agree with the following statements about the transparency and quality of the European Commission Annual Union Work Programmes (AUWP)? Sample size: N = 50

[266] Acceptance refers to how widely accepted the harmonised standards are within your industry in terms of being recognised by businesses. Implementation pertains to the extent to which the harmonised standards are being used within the industry. Adherence refers to how consistently the harmonised standards are being followed or complied with across the industry.

[267] Targeted Survey Industry Q33: On a scale of 1 to 5, where 1 represents 'Not Accepted at All' and 5 represents 'Widely Accepted', how would you rate the acceptance of harmonised standards within your organisation? Please rate the level of acceptance for all the categories. Sample size N = 50.

to the fact that international standardisation bodies do not guarantee their participation like European Standardisation Organisations. In addition, the level of resources that they can dedicate to international standardisation are limited because they focus on European standardisation. Secondly, due to the growing areas of standardisation, they indicated that they would require additional resources to cover all their priorities areas.

- **National societal organisations representing consumers, workers and environmental protection**: Interviews with Annex III organisations, public authorities and national societal organisations revealed that national societal organisations are not adequately represented in National Standardisation Bodies. In addition, their representation significantly varies across Europe. One consumer organisation explained that in their view societal representation is higher in Northern Europe compared to Eastern Europe. Interviews indicated that there are two barriers to participation for national societal representation. The first barrier is the lack of resources to participate effectively, while the second barrier is the lack of expertise in standards. Furthermore, interviews revealed that standardisation is just one of the various activities conducted by national societal organisations, as opposed to Annex III organisations.
- **Research and academic community**: Interviews with industry associations, companies and research and academic stakeholders indicated that the research community does not often participate in standardisation activities. Interviews revealed that this is caused by the incentive structure of research and academic work. Interviewees explained that researchers and academics are rewarded professionally by focusing on academic publications rather than standardisation work. As a consequence, researchers and academics devote less time and budget to standardisation than academic publishing. Furthermore, interviewees agree that low participation of researchers and academics may cause difficulties in the standardisation of emerging technologies including quantum computing, green energy and smart cities.
- **National authorities**: Interviews with industry associations, companies, Annex III organisations, public authorities, and one consumer organisation indicated that national authorities do not adequately participate in national standardisation activities. Interviewees explained that national authorities have low budgets for standardisation and that some National Standardisation Bodies do not effectively involve them. Interviews with national authorities from also reveal national differences in participation. While both authorities communicate and coordinate standardisation work with their national public authorities, one authority has a more direct relationship with the national standardisation body which includes detailed discussions of planned standardisation work. Both authorities carry public consultations to gather information on public authorities' priorities in relation to standards. However, one authority expressed more concerns on the availability of resources than the other. Interviews with industry associations, companies, Annex III organisations, public authorities, and one consumer organisation indicated that

there are negative consequences caused by low participation of public authorities in standardisation on the market and protection of societal interests.

- **People with disabilities**: One interview with disability expert in standardisation indicated that there are structural obstacles preventing participation of people with disabilities and their representatives (Disabled Persons Organisations, DPOs), including, financial barriers stemming from the ESOs or NSBs / NCs / NSOs participatory fees, lack of accessibility of standardisation procedures, documents and meetings. Moreover, there seems to be a lack of adequate accommodation for experts with disabilities to participate in relevant Technical Bodies. Finally, there is unbalanced representation and influence. Resources constraints do not allow DPOs to cover all the relevant TCs in order to ensure that the needs of people with disabilities are systematically considered when drafting standards.
- **Open-source software community**: Interviews with the European Commission, researchers and academics indicated that there is not enough participation from the open-source software community. This is due to the scattered nature of the community. However, one interview with Commission experts suggested that the open-source software community should be more engaged in the standardisation activities given the importance of open source for digital policy and innovation.

EQ3. To what extent has the Regulation 1025/2012 achieved its objectives related to broadening the use of "fora and consortia" technical specifications in public procurement?

The consultations collected relevant data on the extent to which the Regulation achieved its objectives related to broadening the use of "fora and consortia" technical specifications in public procurement, specifically on:

- The effectiveness of ICT technical specifications in enhancing interoperability in public procurement
- Impacts of the use in EU legislation of ICT technical specifications beyond the area of Public Procurement as an alternative to European standards by the ESOs or to international standards

Regarding the Regulation's achievement of its overall objective of broadening the use of ICT standards in public procurement, data from the public consultation showed that 15% of stakeholders consulted saw success to a large extent, 26% to a moderate extent, but 44% did not know, and 12% believed it was achieved to a small extent. A subgroup analysis of responses according to stakeholder type, organisational size and industry sector, in the case of industry associations and businesses, revealed minimal differences among the responses provided by different categories of stakeholders[268].

The targeted survey for industry stakeholders revealed significant uncertainty regarding the impact of ICT technical specifications for public procurement under

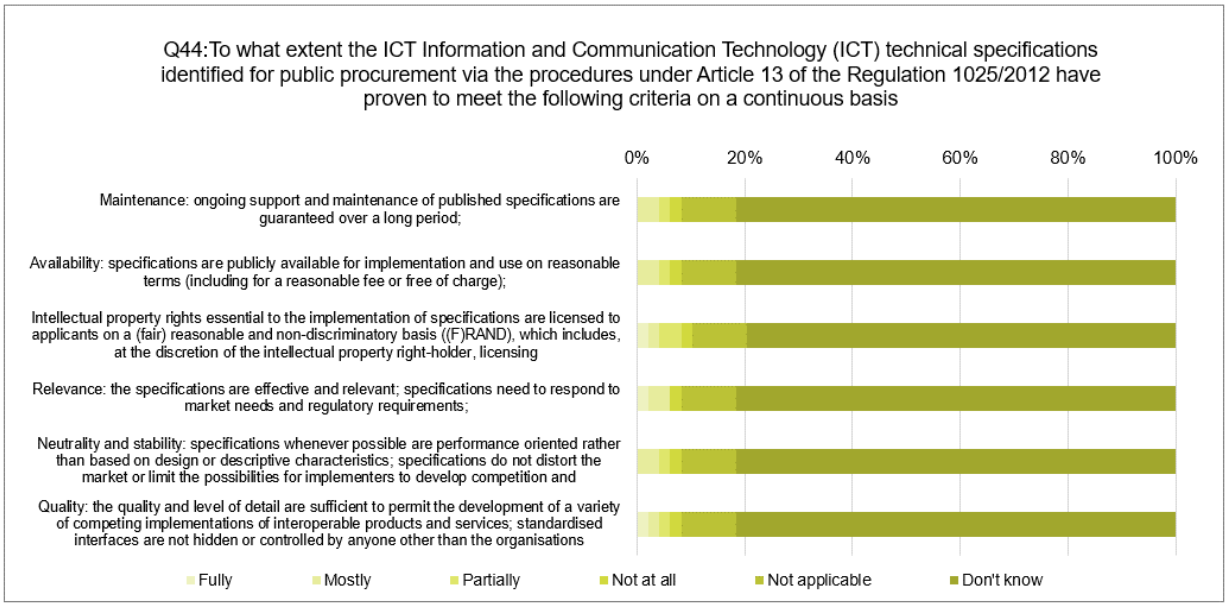
[268] Public consultation Q9: To what extent has the Regulation (EU) 1025/2012 achieved its general objectives? Sample size: N = 254

Article 13 of Regulation 1025/2012.[269] A majority of respondents (62%) indicated they were unsure about the impact of these specifications on their organisation. Among those who provided a clear answer, 18% reported a moderate impact, while 2% felt there was a significant impact. A smaller group noted slight (4%) or no impact at all (14%).

When national authorities (n=23) were asked in the public consultation to evaluate how effectively the Regulation's process has facilitated the identification of ICT technical specifications for public procurement and **enhanced the overall efficiency of the procurement process**, the responses were mixed. A significant portion, 57% reported that they 'don't know' the extent of its impact. Meanwhile, 30% indicated that the process has been beneficial to a moderate extent, with 9% seeing benefits to a small extent, and only 4% perceiving a large extent of improvement[270].

Similarly, regarding the compliance of these ICT specifications with key criteria (i.e. maintenance, intellectual property rights, relevance, neutrality, stability, and quality), a large majority of the industry stakeholders (80-82%) expressed uncertainty, indicating a lack of clear information on whether the specifications consistently meet these requirements[271].

Figure 0.8 Industry and companies views on ICT technical specifications identified for public procurement meeting specific criteria (N=50)



When asked about the adequacy of the procedures outlined in Article 13 for identifying ICT specifications for public procurement, 76% of industry stakeholders were unsure.

[269] Targeted Survey Industry Q43: To what extent the Information and Communication Technology (ICT) technical specifications identified for public procurement via the procedures under Article 13 of the Regulation 1025/2012 have had an impact on your organisation? Sample size N = 49.

[270] Public consultation Q11: To what extent has the process defined by the Regulation facilitated the identification of ICT technical specification for public procurement referencing, and made the overall public procurement process more efficient? Sample size (stakeholder group 'national authorities') = 23

[271] Targeted Survey Industry Q44: To what extent the ICT Information and Communication Technology (ICT) technical specifications identified for public procurement via the procedures under Article 13 of the Regulation 1025/2012 have proven to meet the following criteria on a continuous basis? Sample size N = 49.

Only a small percentage (6%) considered the procedures partially adequate, with 4% rating them as mostly adequate and 4% as inadequate[272].

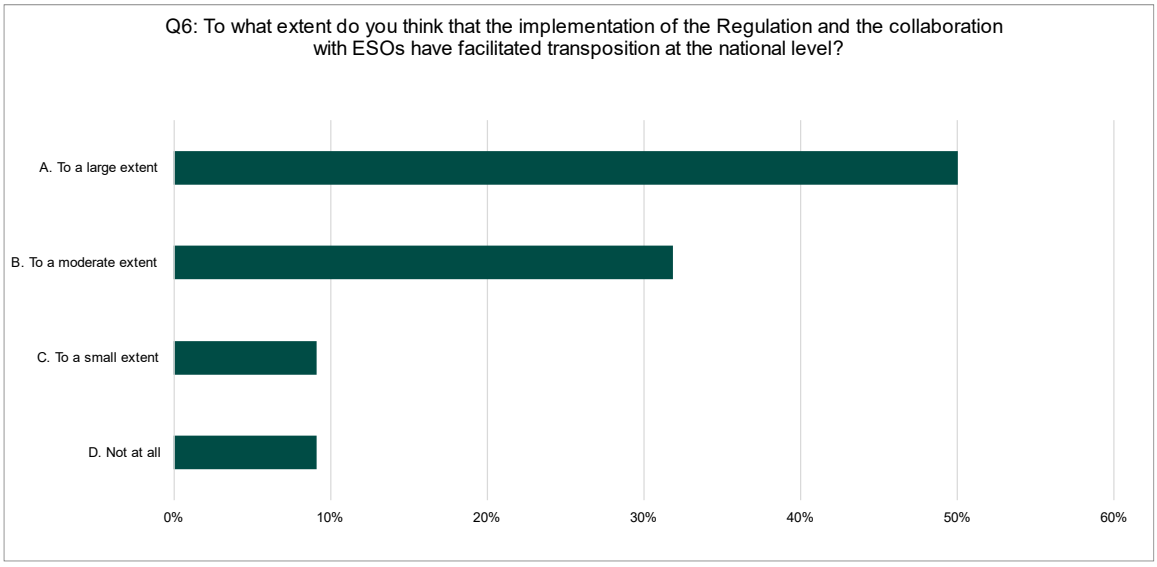
The targeted survey with industry stakeholders also revealed that most of them (62% agree or strongly agree answers) believe that businesses become more competitive when public procurement adopts common ICT technical standards[273].

Interviews with members of the multi-stakeholder platform on ICT standardisation and the European Commission experts revealed that the process is generally viewed as effective. However, its effectiveness diminished when it was put it on hold. One interview with European Commission experts revealed that this was mainly due to the effects of the James Elliot Case on the assessment of standards done by the Commission.

EQ4. To what extent has the Regulation achieved its objectives related to removing ambiguities in the legal framework?

The targeted survey conducted among NSBs/NCs gathered data on the extent to which the Regulation has achieved its objectives of removing ambiguities in the legal framework. Half of the respondents indicated that the Regulation and the collaboration with ESOs have facilitated the transposition of standards at the national level to a large extent, with another 32% stated it was to a moderate extent. However, a small percentage (18%) felt that the process was only marginally effective or not effective at all[274].

Figure 0.9 National Standardisation Bodies' (NSBs) views on how the implementation of Regulation and collaboration with ESOs affect national-level transposition.



Regarding formal objections, interviews with two public authorities revealed that the engagement by public authorities could improve the process. The interviewees

[272] Targeted Survey Industry Q45: To what extent you would consider the procedures in Article 13 for identifying the Information and Communication Technology (ICT) technical specifications for public procurement are adequate and why? Sample size N = 50.
[273] Targeted Survey Industry Q35: Do harmonised standards contribute effectively to enhancing the competitiveness of European businesses within the Single Market? Sample size N=50.
[274] Targeted Survey NSBs Q6: To what extent do you think that the implementation of the Regulation and the collaboration with ESOs have facilitated transposition at the national level? Sample size N=22.

recognised the importance of participating in the process. However, they noted that resource barriers often hinder their participation in the process.

EQ5. What are the economic and social impacts of the Regulation 1025/2012 on the internal market, consumers' safety, workers' protection, and environmental protection?

The consultations collected data on the economic and social impacts of the Regulation. Specifically, the data collected cover:

- Harmonised standard impact in facilitating growth, innovation and increasing competitiveness of European businesses, especially SMEs
- Harmonised standards impact, in conjunction with the manufacturers' self-assessment and, where applicable, the conformity assessment performed by notified bodies, on consumers' safety, workers' protection and environmental protection

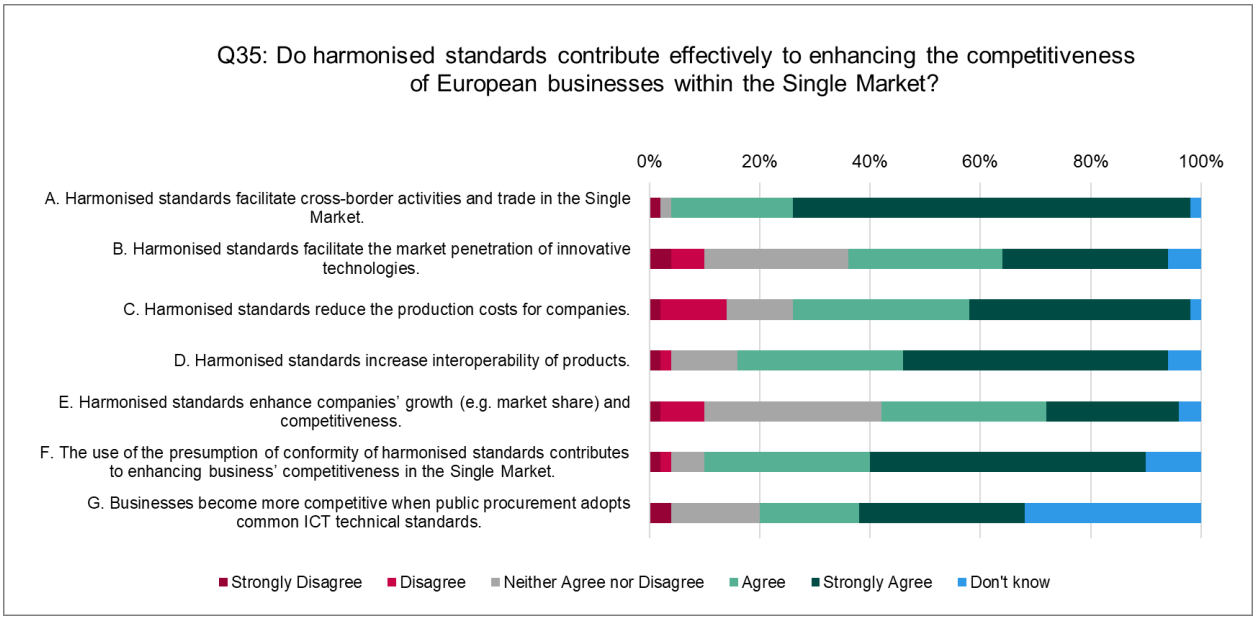
The data collected from the public consultation indicated that most respondents (55%) strongly agree that harmonised standards facilitate cross-border activities and trade within the Internal Market, with 32% agreeing. Respondents reported that market deployment of innovative technologies is also supported by these standards, with 26% strongly agreeing and 35% agreeing.[275] In terms of cost reduction, 32% strongly agree that harmonised standards reduce production costs for companies, and another 32% agree, while 17% do not know. Regarding compliance costs, 41% (n = 105) strongly agree that these are reduced, and 28% agree, while 15% do not know. Additionally, 44% strongly agree that standards increase interoperability of components and products, with 33% agreeing.

With regards to the responses provided in the public consultation by SMEs (N=66), 37% strongly agree that harmonised standards facilitate their access to the EU market, while 25% agree, and 20% do not know. However, opinions are more divided on whether standards enhance companies' growth, with 26% strongly agreeing, 20% agreeing, 22% neither agreeing nor disagreeing, and 26% do not know. Lastly, 22% strongly agree that standards enhance productivity, with 30% agreeing, though 17% were uncertain and 22% did not know.

The targeted survey with industry stakeholders indicated that they strongly support the role of harmonised standards in enhancing European businesses' competitiveness within the Single Market. A majority (72%) agree that standards facilitate cross-border trade, while 58% see them aiding the market penetration of innovative technologies, though 26% remain neutral. Standards also contribute to reducing production costs (72%) and improving product interoperability (78%), with strong support for their impact on competitiveness (54%). Overall, harmonised standards are viewed as important for trade, cost reduction, and competitiveness.

[275] Public consultation Q19: To what extent do you agree/disagree with the following statements about European standards and standardisation deliverables' impact in the competitiveness of European businesses within the internal market? Sample size N = 254.

Figure 0.10 Industry and companies views on the contribution of harmonised standards in enhancing competitiveness of European businesses within the Single Market (N=50)



Furthermore, the targeted survey for Annex III organisations asked questions related to the impact of the Regulation on consumers' safety, environmental protection and workers protection.

- **Consumers' safety**: In response to the question about whether products compliant with voluntary harmonised standards meet quality and safety benchmarks,[276] it was observed that such products have a comparable incidence of safety violations and non-compliance findings to those certified under mandatory technical regulations.
- **Environmental protection**: harmonised standards are seen as moderately effective in promoting environmental sustainability and reducing environmental impact, but their influence on broader EU environmental policymaking is uncertain.[277] The extent to which harmonised standards promote environmental sustainability was rated as "Moderate", while the effectiveness of harmonised standards in minimising environmental impact and adhering to eco-friendly protocols received a "High" rating. However, when considering the impact of harmonised standards on broader environmental policymaking within the EU, the submitted response was " Not enough information: We do not have enough information to evaluate the environmental impact of products put on the market under voluntary harmonised standards."[278]

[276] Annex III Survey question Q19: To what extent do you believe that products compliant under voluntary harmonised standards meet quality and safety benchmarks for consumers? Select only one option. Please consider the incidence of safety violations, findings from compliance audits or assessments, and comparisons with products certified under mandatory technical regulations or through self-assessment and notified body assessments. Sample size: N = 1

[277] Targeted Survey Annex III organisations Q20: On a scale of 1 to 5, where 1 represents 'Very Low' and 5 represents 'Very High', how would you rate the support of harmonised standards to achieve EU environmental objectives? Sample size: N = 1

[278] Targeted Survey Annex III organisations Q21: How would you assess the environmental impact of products compliant under voluntary harmonised standards in comparison to those certified under other EU regulatory assessment frameworks? Sample size: N = 1

- **Workers' safety**: The same targeted survey also revealed that manufacturing under voluntary harmonised standards shows moderate improvements in workers' safety and welfare compared to traditional regulatory compliance frameworks[279]. This indicates that there are some improvements in areas such as incident rates, working conditions, health and safety practices, and overall worker welfare for products manufactured under voluntary harmonised standards.

Interviews with industry associations and companies generally indicated positive impacts of the Regulation on competitiveness in the Single Market:

- **Conformity assessments**: Interviews with industry associations and companies revealed that the Regulation streamlined conformity assessments and decreased technical barriers to trade. They indicated that before the Regulation, trade in the internal market was difficult due to the prevalence of national standards.
- **Costs and growth**: Although many companies report cost reductions as a result of using harmonised standards, they reported that they not inherently lead to growth and enhanced productivity. Companies indicated that when cost reductions are uniform across companies, the competitive edge linked to cost competitiveness achieved through the use of harmonised standards decreased.
- **Innovation**: Interviews with stakeholders revealed mixed opinions on innovation. Some companies and industry associations doubt that harmonised standards foster innovation, arguing that legislative requirements lag behind the pace of industry innovation. Additionally, some industry associations believe that industry-driven standards generate more innovation. They argue that industry is more interested in innovations than policymakers. However, this view is contested by some companies. Many revealed that firms sometimes block innovation to maintain their competitive advantage.

EQ6. How cost-efficient are the administrative processes and reporting requirements for different parties generated by Regulation 1025/2012? The survey collected data on administrative requirements costs for National Standardisation Bodies (NSBs/NCs/NSOs). Data were provided by 19 National Standardisation Bodies (NSBs/NCs/NSOs), representing 55% of all such organisations. We asked National Standardisation Bodies (NSBs/NCs/NSOs) to estimate for one standard per year the number of full-time-equivalent that they employ on the activity on average and the working days to complete the tasks and the average costs to employ a full-time staff member for one day.[280] To minimise the influence of outliers on the statistics that we

[279] Targeted Survey Annex III organisations Q22: How does workers' safety and welfare compare in the manufacturing of products under voluntary harmonised standards versus those produced under traditional regulatory compliance frameworks? Sample size: N = 1

[280] Targeted Survey National Standardisation Bodies Q9: We are seeking to better understand the time and staffing resources that your organisation dedicates to transparency of operations and cooperating with other Standardisation Bodies and the European Commission. Please help us by indicating the Full-Time Equivalents (FTEs) and the average number of days per year spent for each of the following activities. In case it is not possible for you to give figures feel free to provide a range or a qualitative assessment. Sample size: N = 22

Targeted Survey National Standardisation Bodies Q10: If you wish, you can help us to better estimate the costs of transparency and cooperation requirements of the Regulation 1025/2012 by indicating the average cost for your organisation to employ a full-time staff member for one day. Sample size: N = 22

computed, we used a technique called winsorisation which limits the effect of outliers.[281] The table below presents the average resources that National Standardisation Bodies (NSBs/NCs/NSOs) use for administrative requirements. The results show that the average of the reported estimates vary significantly according to the estimation method. For a full analysis of the costs please consult Chapter 4.

Table: Average resources that National Standardisation Bodies use annually to fulfil administrative requirements of the -Regulation

Data	Statistics	Administrative requirements	Average FTEs in a year	Average number of days in a year
Original data	**Geo-metric mean**	A. Requesting other standardisation bodies' draft standards for review.	6	9
		B. Commenting on requested drafts of standards.	9	6
		C. Addressing comments from other Standardisation bodies on requested drafts of standards.	6	8
		D. Sharing best practices with other National Standardisation Bodies to involve SMEs in standardisation activities.	7	2
		E. Drafting your Work Programmes.	3	2
		F. Notification of your Work Programmes to the ESOs, European Commission and Member States.	6	4
		G. Reporting duties set in the Regulation	4	2
Winsorised data	**Arith-metic mean**	A. Requesting other standardisation bodies' draft standards for review.	1	1
		B. Commenting on requested drafts of standards.	1	1
		C. Addressing comments from other Standardisation bodies on requested drafts of standards.	1	1
		D. Sharing best practices with other National Standardisation Bodies to involve SMEs in standardisation activities.	1	2
		E. Drafting your Work Programmes.	2	2

281 Winsorisation limits the effect of outliers in a dataset by replacing them with the nearest values within a defined percentile range, rather than removing them, thereby capping extreme values to lessen their impact. We winsorised data at the 10th and 90th percentiles. If a value was less than the 10th percentile we replaced it with the 10th percentile. If the value was more than the 90th percentile we replaced it with the 90th percentile. Please see Annex II for more details on the methodology.

Data	Statistics	Administrative requirements	Average FTEs in a year	Average number of days in a year
		F. Notification of your Work Programmes to the ESOs, European Commission and Member States.	1	1
		G. Reporting duties set in the Regulation	2	2

A comparison of the resources across the two estimates reveals that National Standardisation Bodies allocate the most resources to three key activities: B) commenting on requested drafts of standards, C) addressing comments from other standardisation bodies, and D) sharing best practices to engage SMEs. These activities account for a larger proportion of the overall resources compared to other tasks, indicating where the majority of their efforts and resources are concentrated controlling for different estimation methods.

The results of the survey indicate that National Standardisation Bodies can spend between € 100 and € 710 to employ a full-time staff member for one day[282].

EQ7. How cost-efficient is the development of 'harmonised standards' and 'European standardisation deliverables' throughout the process of standardisation requests?

The targeted surveys collected data on the resources that Annex III organisations and businesses use to participate in standardisation activities. These data were collected to estimate the costs and benefits associated with Regulation 1025/2012. For a full analysis of the costs please consult Chapter 4.

In the targeted survey for Annex III organisation, they provided data on the average number of experts that they employ for participation in technical discussions **for a single standard per year**. Before the analysis we did not conduct outlier tests on the data because our sample is complete with all observations. On average, Annex III organisations employ two experts for their participation in technical discussions for each standard.

Interviews with Annex III organisations suggested that the administrative burden of the Regulation has increased over the years. Annex III organisations indicated that the level of detailed required in their reporting has increased leading to greater costs.

In addition, the targeted survey collected data on the resources that businesses use to participate in standardisation activities. We distinguished between SMEs and large businesses[283]. We asked businesses to estimate for a single standard a year the average number of full-time-equivalent that they employ on the activity, the hourly labour costs, the number of Technical Meetings, and the ancillary costs (travels, meals, materials,

[282] The lower average is the arithmetic mean of winsorised data, the upper average is the geometric mean of original data.

[283] Targeted Survey Industry Q24: We are seeking to better understand the resources that your organisation dedicates to participating in standardisation activities with NSBs/NCs and ESOs. How much time and resources on average does your organisation spend per year to participate in the following standardisation activities of one standard?
Targeted Survey Industry Q25: Could you please provide an estimate of the average number of meetings your organisation typically attends annually to work on a harmonised standard?

etc.). To minimise the influence of outliers on the averages, we used a technique called winsorisation which limits the effect of outliers[284].

The collected data for large businesses reflect a subset of 19 responses to the industry targeted survey from large companies (250 or more) which corresponds to 38% of the total survey sample. The table below presents the average resources that large businesses use annually to participate in the development of a single standard[285].

Table: Average resources that large businesses use annually to participate in the development of a single standard

Breakdown of costs	Average FTEs	Average hourly cost	Average ancillary costs	Average number of meetings
A. Proposal and acceptance process of new work items	1	€ 104	€ 844	
B. Participation in technical discussions on proposals	2	€ 110	€ 3 083	21
C. Submission of comments on draft standards or deliverables	2	€ 136	€ 1 482	
D. Revision of existing European standards or deliverables	1	€ 138	€ 1 232	
E. Dissemination and awareness-building about European Standards	1	€ 78	€ 444	

The collected data for SMEs reflect a subset of 31 responses of the industry targeted survey from medium (50 to 249 employees), micro (1 to 9 employees), and small (10 to 49 employees), representing 62% of companies surveyed. The table below presents the average resources that SMEs use annually to participate in the development of a single standard[286].

Table: Average resources that SMEs use annually to -participate in the development of a single standard

Breakdown of costs	Average FTEs	Average hourly cost	Average ancillary costs	Average number of meetings
A. Proposal and acceptance process of new work items	1	€ 85	€ 550	
B. Participation in technical discussions on proposals	1	€ 85	€ 1,656	12

[284] Winsorisation limits the effect of outliers in a dataset by replacing them with the nearest values within a defined percentile range, rather than removing them, thereby capping extreme values to lessen their impact. We winsorised data at the 10th and 90th percentiles. If a value was less than the 10th percentile we replaced it with the 10th percentile. If the value was more than the 90th percentile we replaced it with the 90th percentile. Please see Annex II for more details on the methodology.
[285] These figures are the arithmetic means of winsorised data.
[286] These figures are the arithmetic means of winsorised data.

Breakdown of costs	Average FTEs	Average hourly cost	Average ancillary costs	Average number of meetings
C. Submission of comments on draft standards or deliverables	1	€ 85	€ 1,133	
D. Revision of existing European standards or deliverables	1	€ 85	€ 1,453	
E. Dissemination and awareness-building about European Standards	1	€ 183	€ 1,521	

The results show that large businesses generally employ more resources than SMEs to participate in standardisation activities. Moreover, the results indicate that large businesses have higher labour and ancillary costs and participate in more meetings than SMEs.

Interviews with industry associations, companies and Small Business Standards indicated that SMEs are less able to sustain the costs of participating in standardisation activities compared to large companies. This results in lower participation rates of SMEs.

In addition, interviews with industry associations and companies indicated that as the time of citation of harmonised standards in the OJ increases the costs of placing products and services on the market increase. This is due to the fact that companies wait longer times to use harmonised standards for conformity assessments and when standards are outdated their production processes does not follow the pace of the new technical requirements, hence they have to wait to adjust production towards the updated standards.

EQ8. To what extent have the objectives of the Regulation been relevant to address wider strategic needs of the European standardisation system explained in COM (2011) 311?

The targeted survey with industry stakeholders collected data on their views on whether the objectives of the Regulation been instrumental to address the problem of "Fora and Consortia Standards" not being referenced in public procurement of ICT (please refer to Annex III, evaluation sub-question "EQ8.2").

Most business stakeholders indicated that they do not know whether the procedure of identification of ICT common technical specifications have been instrumental to address the problem (76%).[287] Only 4% of respondents indicated that these are mostly adequate.

EQ9. To what extent are the objectives of the Regulation still fit for purpose considering the new needs explained in the 2022 Standardisation Strategy?

[287] Targeted Survey Industry Q45: To what extent you would consider the procedures in Article 13 for identifying the Information and Communication Technology (ICT) technical specifications for public procurement are adequate and why? Sample size: N = 50, Distribution of responses: Don't know - 76% (n=38); Mostly - 4% (n=2); Not applicable - 10% (n=5); Not at all - 4% (n=2) Partially - 6% (n=3).

The public consultation revealed stakeholders' feedback on the extent to which the provisions of the Regulation were suitable for addressing the wider strategic objectives, as outlined in the 2022 EU Strategy on Standardisation (COM (2022) 31)[288].

For the development of future market needs, 29% of respondents believed it was suitable to a large extent, 13% to a small extent, while 34% see moderate suitability and 21% reported they don't know. In addressing **urgent market needs**, 28% reported it is suitable to a large extent and 26% to a moderate extent, but 19% only see a small suitability while 18% reported they don't know. **Regarding the development of service standards**, 23% believed it was suitable to a large extent, 17% to a moderate extent and 14% to a small extent, though 41% did not know. For **ensuring integrity and inclusiveness** in the standardisation system, 34% reported strong suitability, with 27% seeing moderate suitability and 14% a limited suitability, at the same time 19% answered they don't know. **Regarding the EU's role in global standards-setting**, 20% saw the Regulation's suitability as large, while 28% rated it as moderate and 19% as small. With regards to the **promotion of EU democratic values globally** is seen as significantly suitable by 18%, with 31% seeing moderately suitable and 13 % slightly suitable. Finally, for the inclusion of **cutting-edge research in standards-development** is recognised by 25% as significantly suitable, though 27% remain uncertain.

The public consultation also revealed insights regarding stakeholders views on the essential action areas, in light of the need for the ESS to adapt to a rapidly changing environment and align with the Union's strategic goals[289]. A significant 22% of respondents strongly agreed that addressing future standardisation needs and expediting the process is crucial for spurring innovation and preventing competitive disadvantage, while 34% agreed. Similarly, promoting stakeholder involvement and inclusivity to ensure standards meet market and consumer demands was considered an essential action area by 39% strongly agreeing, with 42% agreeing.

Improving cooperation, coordination, and communication among standardisation bodies in the EU was essential for 37% who strongly agreed and 27% who agreed. Raising awareness of the benefits of standardisation for competitiveness, innovation, and sustainability was strongly supported by 41%, and 38% agreed. However, there is less consensus on adapting the ESO/NSB network organisation and procedures for future needs, particularly in technology convergence. While 19% strongly agreed and 34% agreed, 14% disagreed.

The targeted surveys gathered data on stakeholders' views on the reconciliation of public and business interests generated by Regulation (EU) 1025/2012.

- **Among industry respondents to the targeted survey**, 44% believe the ESS achieves this balance to a large extent, while 28% think it does so to a moderate extent. However, a smaller portion (10%) reported that the system only reconciles

[288] Public consultation Q14: To what extent are the provisions of the Regulation suitable for addressing the wider strategic objectives, as outlined in the 2022 EU Strategy on Standardisation (COM(2022) 31)? Sample size: N = 254

[289] Public consultation Q30: Considering the need for the ESS to adapt to a rapidly changing environment and support the Union's strategic goals, what action areas do you consider essential? Sample size: N = 254

these interests to a small extent, and 4% say it does not reconcile them at all. Notably, 14% of industry stakeholders expressed uncertainty, suggesting room for further clarity on this issue[290].

- **In contrast, the responses from Annex III organisations** to the targeted survey were more varied. Half perceived a moderate alignment between public and business interests, 25% believing the reconciliation occurs to a large extent, and another 25% seeing it to a small extent[291].
- **Results from the National Standardisation Bodies targeted survey showed that, 64% believed that the European Standardisation System effectively balances public interest with business interests to a large extent.** However, a few highlighted areas where public and business interests may diverge, such as the protection of copyright in harmonised standards or the alignment of standardisation requests with business priorities. Respondents who indicated that they do not believe that the system balances public interest with business interests agreed that the conflicts arise when standardisation requests are not in line with business interests[292].

EQ10. To what extent is the Regulation 1025/2012 coherent with current EU policies, priorities, and terminologies, ensuring a unified approach within the EU legislative framework. According to the data collected from the public consultation,[293] Artificial Intelligence (AI) stands out as a policy area where the ESS should improve its presence, with 58% of respondents recognising its importance (the majority being companies (20%) and Industry associations (27%)). Renewable Energy Technologies also received strong recognition, with 50% (21% companies, 28% industry associations, 10% NSBs, 6% national authorities, 4% research institutions) acknowledging its significance. For 5G and Future Telecommunication Networks, 38% see it as a potential new policy area. Digital Health is another area where 54% of respondents recognise its importance. In contrast, there is significant uncertainty among all stakeholder groups around Quantum Computing and Blockchain and Distributed Ledger Technologies, with 59% of respondents replying that they do not know if the ESS should improve its presence there. Similarly, for Biotechnology and Gene Editing, 72% do not know and only 21% recognise its importance.

Space Technologies and Robotics have 43% and 39% of respondents, respectively, agreeing that the ESS should improve its presence there. Lastly, the category of **New Materials and Other technologies** both show considerable uncertainty, with 70% and 76% do not know, respectively.

[290] Targeted Survey Industry Q32: To what extent do you consider that the European Standardisation System, as conceived in the Regulation 1025/2012, allows to reconcile the public interest with business interests? Sample size: N = 40

[291] Targeted Survey Annex III organisations Q17: To what extent do you consider that the European Standardisation System, as conceived in the Regulation 1025/2012, allows to reconcile the public interest with business interests? Sample size: N = 4.

[292] Targeted Survey National Standardisation Bodies Q13: To what extent do you consider that the European Standardisation System, as conceived in the Regulation 1025/2012, allows to reconcile the public interest with business interests? Sample size: N = 22

[293] Public consultation Q24: Can you identify any new policy area where the ESS should improve it presence? competitiveness of European businesses at the global level? Sample size: N = 254

On the other hand, **the targeted survey collected data from National Standardisation Bodies** on whether they believe that implementation of the Regulation has been coherent with national policies affecting the procedures of standards development at the national level.

Most respondents (86%) indicated that the Regulation's implementation is fully coherent with national standardisation policies. Only a small fraction (10%) reported partial or non-coherence[294].

Table: National Standardisation Bodies views on the coherence of the implementation of the with national policies affecting the procedures of standards development at the national level

Response options	Percentage of responses
A. The implementation of the Regulation has been fully coherent with national standardisation policies	90% (n = 18)
B. The implementation of the Regulation has been coherent with national standardisation policies to a small extent	5% (n = 1)
C. The implementation of the Regulation has not been coherent with national standardisation policies	5% (n = 1)
D. Don't know	0% (n = 0)
Total	N = 22

With respect to the coherence of the Regulation with the General Product Safety Regulation (GPSR), one interview with European Commission experts highlighted some challenges on the consistency of definitions in the Regulations. The definition of harmonised standards in the Regulation 2015/2012 does not cover technical specifications requested for the GPSR. Experts in the European commission noticed that since harmonised standards in Art. 2 of the Regulation are defined as "European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation", they do not cover those requested for the GPSR. s**This generates incoherence between the mechanism through which harmonised standards are developed and those of the GPSR and applies to all the provisions except those stated by the revised Article 10 on standardisation requests**. As a result, challenges arise in terms of applicable legislation and liability of producers and the Commission. Nevertheless, appropriate services of the Commission confirmed that a discussion is ongoing to solve this issue.

EQ11. To what extent are the various elements of the Regulation 1025/2012 coherent internally with one another?

Evidence for this question is based on secondary desk research.

[294] Targeted Survey National Standardisation Bodies Q15: To what extent do you consider that the implementation of the Regulation has been coherent with national policies affecting the procedures of standards development at the national level? Sample size: N = 22

EQ12. Is there additional value resulting from the Regulation, compared to what could be achieved merely at national level?

The public consultation revealed stakeholders' views regarding the areas where Regulation (EU) 1025/2012 provided most added value compared to not having this legal framework in place.[295] Most respondents agreed on the following added value that the Regulation (EU) 1025/2012 has provided compared to not having this legal framework in place: 75% claims it facilitates conformity assessment, 78% claims that it aids product compliance, and 69% claims that it helps removing trade barriers. Additionally, 69% noted increased adoption of a common technical language, and 55% saw more opportunities to introduce products in the Single Market. Fewer respondents agreed on reducing transaction costs (49%) and aligning European and international standards (44%). Notably, 67% did not know about other unspecified areas.%**Interviews with industry associations and companies revealed that the Regulation streamlined conformity assessments and decreased technical barriers to trade**. They indicated that before the Regulation, trade in the internal market was difficult due to the prevalence of national standards.%Interviews with Annex III organisations revealed that without the Regulation their participation in European standardisation activities would have been weak. In particular, ANEC has stated that without Union Financing they would have struggled to effectively represent consumers' interests in standardisation.%EQ13. To what extent do the issues addressed by the measure continue to require action at EU level?

Interviews with industry associations and the European Commission indicated there is a need for EU action on education about standardisation and standards. This is due to demographic change that sees the number of experts currently available retiring from standardisation activities and a lower pool of skilled younger experts to replace them.

Validation workshop

The workshop was held online on 6 November 2024, with the key objective of presenting the preliminary findings of the evaluation Study of the **Regulation (EU) No 1025/2012** on European standardisation system. Invitations were extended to all relevant stakeholder groups.

Over **470** people registered for the workshop with participants representing more than **10 different stakeholders groups** including Companies / Business, National Standardisation Body / National Committee / National Standardisation Organisation, Trade and Business Association, academia and research institutes. A total of **220** participants attended from various European countries: **Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden**.

The session included an introduction from a representative of the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG

[295] Public consultation Q13: In your opinion, where has Regulation (EU) 1025/2012 provided most added value compared to not having this legal framework in place? Sample size: N = 254.

GROW) and was followed by a detailed overview from the study team, covering the study methodology, and preliminary results.

To streamline interaction and gather immediate feedback, participants took part in **live polls** through the SLIDO tool, providing input to validate the study's primary findings. Attendees also submitted open questions via SLIDO, which will be addressed and included in the final report.

Main takeaways

During the workshop, the audience **validated the main findings from the study**. A summary of the main questions posed to the audience can be found below.

Effectiveness – Objective 1: Enhancing speed of the standard development process

In their answers to the question "Based on your experience, do you perceive that the time needed to develop one hEN has decreased since 2013, compared to the previous years?", participants provided the responses below:

- Yes, the timeline has generally decreased **38%**
- Yes, but it really depends on specific cases **32%**
- No, significant reduction was not observed **17%**
- I don't know **13%**

In their answers to the question "In your opinion what are the main reasons for delays in the current system?", participants provided the responses below:

- Being fast, while at the same time ensure inclusiveness **16%**
- The impact of case law has increased the OJEU publication time **36%**
- The increasing pace of legislation has put pressure on deadlines and on the ability of ESOs to deliver in time **40%**
- Poor communication and coordination between the European Commission, including HAS consultants, and the ESOs **71%**
- Insufficient allocation of resources (such as funding, personnel, or information) within the ESS **33%**

Effectiveness – Objective 2: Enhancing stakeholders' participation and inclusiveness

In their answers to the question "**Do you agree that the Regulation has increased the effective participation of stakeholders**?", participants provided the responses below:

- Yes, mainly for Annex III organisations at the EU level. **49%**
- Yes, mainly for SMEs at national level. **18%**
- Yes, mainly for the research community at the EU level. **13%**
- Yes, mainly for people with disabilities at the EU level. **3%**
- Yes, mainly for public authorities at national levels. **10%**

- Yes, all of the above **35%**
- No, the Regulation has not significantly increased participation for these groups at either the EU or national level. **14%**

Effectiveness – Objective 3: Expanding use of ICT technical specifications in public procurement

In their answers to the question "In your opinion, has the mechanism for identifying common ICT technical specifications for public procurement been effective?", participants provided the responses below:

- Yes, to a large extent **13%**
- Yes, to a moderate extent **18%**
- Yes, but only to a small extent **51%**
- Not at all **18%**

Effectiveness – Objective 4: Removing ambiguities in the legal framework

In their answers to the question "In your opinion what are the reasons for the challenges that emerged in the formal objection mechanism?", participants provided the responses below:

- Limited engagement in standardisation activities by market surveillance authorities **79%**
- Ambiguity surrounding the procedural guidelines **39%**
- Extended duration required for standard revisions **11%**
- Concerns regarding the thoroughness of compliance assessments for submitted standards **15%**

Efficiency

In their answers to the question "**Do you agree that the overall benefits for the economy are still higher than costs?"**, participants provided the responses below:

- Yes, benefits are always higher than costs and they bring about benefits for European stakeholders at both the EU and international level **68%**
- Yes, mainly for economic benefits at the EU level **33%**
- Yes, but it depends on the sector **17%**
- Yes, but benefits for the economy are not so high compared to costs **1%**
- Yes, but the economic benefits are limited to the presumption of conformity **9%**
- No, the costs are higher than the economic benefits **6%**

In their answers to the question "**Do you agree that the overall benefits for society are still higher than costs?"**, participants provided the responses below:

- Yes, benefits are always higher than costs and they bring about benefits for European stakeholders at both the EU and international level **74%**
- Yes, but mainly for societal benefits at the EU level **25%**
- Yes, but benefits for society are not so high compared to costs **5%**
- No, the costs are higher than the societal benefits **2%**

Coherence

In their answers to the question "Did you experience any contradictions or overlaps among activities established by the Regulation?", participants provided the responses below:

- No, the Regulation is internally consistent **68%**
- Yes, I am aware of contradictions and overlaps in the provisions of the Regulation **14%**
- I don't know **18%**

In their answers to the question "Based on your experience, do you think that the Regulation is coherent with other European policies or initiatives in standardisation?", participants provided the responses below:

- Yes, to a large extent **44%**
- Yes, to some extent **36%**
- Only to a small extent **9%**
- No, not at all **4%**
- I don't know **6%**

EU added value

In their answers to the question "Has the Regulation generated an added value compared to what could have been accomplished at the national level?", participants provided the below answers:

- Yes, mainly for facilitating growth **51%**
- Yes, mainly for generating innovation **14%**
- Yes, mainly for enhancing growth **27%**
- Yes, mainly for ensuring the inclusiveness of the system **32%**
- Yes, but in comparison there has not been a value added in terms of international competitiveness and influence on standardisation **26%**
- Yes, and continued EU action is needed due to emerging challenges **47%**
- No, there has not been any added value **2%**

Relevance

In their answers to the question “Which of the following original objectives of the Regulation is still relevant nowadays?”, participants provided the responses below:

- Obj. #1 Enhancing speed of the standard development process **14%**
- Obj. #2 Enhancing stakeholders' participation and inclusiveness **17%**
- Obj. #3 Expanding the use of technical specifications in public procurement **3%**
- Obj. #4 Removing ambiguities in the legal framework **16%**
- All the above **50%**
- None of the above **2%**

In their answers to the question “To what extent is the Regulation still fit to support legislation and market throughout the Green and Digital transitions?”, participants provided the responses below:

- To a large extent **63%**
- To some extent **26%**
- To a small extent **6%**
- Not at all **3%**
- I don’t know **2%**

ANNEX VI: FUNDING PROVIDED TO THE EUROPEAN STANDARDISATION ORGANISATIONS

Table: Sum of operating and action grants issued to CEN, CENELEC and ETSI in comparison with their budget (all amounts in k€)

CEN	2017	2018	2019	2020	2021	2022	2023
CEN budget	24 420	22 464	23 933	17 173	16 552	18 769	23 160
Operating grants (commitments)	2 271	2 049	1 939	1 951	1 780	1 922	2 200
Operating grant as a % of the budget	9.3%	9.1%	8.1%	11.4%	10.8%	10.2%	9.5%
Action grants to CEN[296]	17 098	11 340	6 926	7 354	0	10 875	5 524

CENELEC	2017	2018	2019	2020	2021	2022	2023
CENELEC budget	4 593	4 354	4 601	4 052	4 698	4 362	5 091
Operating grants (commitments)	591	713	665	592	534	602	720
Operating grant as a % of the budget	12.9%	16.4%	14.5%	14.6%	11.4%	13.8%	14.1%
Action grants to CENELEC	1 693	0	1 079	1 107	0	0	3 553

ETSI	2017	2018	2019	2020	2021	2022	2023
ETSI budget	22 238	23 561	24 065	21 588	22 005	24 858	26 630
Operating grants (commitments)	2 422	2 390	2 349	2 176	1 739	900	200
Operating grant as a % of the budget	10.9%	10.1%	9.8%	10.1%	7.9%	3.6%	0.8%
Action grants to ETSI	946	1 184	1 645	3 958	0	978	1 606

[296] Action grants to CEN and CENELEC may be transmitted to the affiliated national standardisation bodies that carry out the work and can therefore not be considered as part of the budget of CEN and CENELEC.

Minutes of the workshop organised with scholars and academic experts on the European standardisation system

Date: 22 November 2024
Format: online

Regulation (EU) 1025/2012 provides the legal framework on the principles, procedures, modalities, procedures and financing of how European standards shall underpin EU policies and legislation. With a view to the ongoing evaluation of Regulation (EU) 1025/2012, the Commission organised a specific workshop with 15 scholars and academics, who have pronounced themselves on European standardisation system from a legal, economic and political science perspective, and heard their views regarding recommendations for possible adjustments of the legal framework.

The stakeholder viewpoints can be summarised under the following three areas: (1) transparency and access to standards, (2) governance and participation of stakeholders in the standardisation process; and (3) the role of the European Commission in this process.

Transparency and access to standards.

A number of workshop participants expressed themselves on the need for enhanced transparency and access to harmonised standards in view of the latest jurisprudence of the European Court of Justice. Many participants encouraged to clarify the legal standing of standards and to revise the Regulation to allow for publication of standards in full in the Official Journal of the EU, in line with the principles of constitutional law and the spirit of ECJ jurisprudence. Currently the Regulation envisaged to publish the references of standards, but not the actual texts. Full publication of standards subject to EU harmonisation legislation was considered in line with the transparency and accessibility principles and the rule of law. The question of how to resolve the copyright issue was acknowledged. One scholar suggested to link the work on harmonised standards with transparency requirement for European/national standardisation organisations to obtain financial data on the revenue generated from harmonised standards.

Governance and participation of stakeholders

Some scholars noted that the standards-development organisations – which are governed by private law – were not to be democratised as such. It was cautioned to overly bureaucratise and formalise the process as well.

Many participants highlighted the fact that stakeholder participation in standards-development was to be improved. The rights of stakeholders were to be increased, and the right stakeholder groups – depending on the area that a standard is developed in – were to be invited, including research and technology organisations and public authorities. Opinions differed as to how to achieve this goal. One scholar suggested to strengthen the provisions of Article 5 Regulation (EU) 1025/2012, which encourages and facilitates stakeholder participation, by including clear right and responsibilities for stakeholder

groups in standards-development. It was also suggested to extend the scope of Art. 6 Regulation (EU) 1025/2012 beyond SMEs. It was suggested that transparency and, generally, lowering thresholds for participation in terms of financial, administrative and overly 'time' burdens, was a more effective approach.

Role of the Commission

Participants suggested to clarify and strengthen the role for the Commission in the standards-development and citation process, including regarding the final responsibility for quality control and due diligence. The judgement of the ECJ in the James Elliott case was considered a strong indication in this direction. There was also a suggestion to clarify the procedure for citation in the Official Journal of the EU, which had evolved with a view to recent ECJ jurisprudence and was to be clarified.

Other points raised:

- As a separate point, some participants highlighted the changing nature of standards of moving from product safety to impacting many areas of society and economy, including fundamental rights. The work on the AI standards was a case in point, in which more and more political questions were addressed, and which included many procedural rules and less product specificities. This new role of standards with a socio-economic impact was more likely to increase with the Green and Digital policy objectives and harmonised standards will have to increasingly address socio-economic elements. In these new fields of standards, it was of utmost importance to demonstrate the legitimacy of standards and compliance with the EU constitutional principles. A revision of Regulation (EU) 1025/2012 would present an important opportunity to clarify this new role of standards.
- The issue of IPR was raised, suggesting that a revision of Regulation (EU) 1025/2012 would present an opportunity to clarify disclosure requirements on IPR/patents issues and to increase transparency.

ANNEX VIII: BACKGROUND INFORMATION – KEY ELEMENTS OF REGULATION (EU) NO 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 establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies**, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation.

European standards are adopted by one of the three European standardisation organisations (ESOs), as recognised in the regulation:

- European Committee for Standardisation (CEN)
- European Committee for Electrotechnical Standardisation (Cenelec)
- European Telecommunications Standards Institute (ETSI)

A **harmonised standard** is a European standard adopted by one or more 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 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.

At national level, standardisation is managed by **national standardisation bodies** (NSBs) notified by the Member States and by the EEA countries to the Commission. The NSBs must withdraw all national standards which conflict with harmonised standards. The NSBs have the exclusive power to adopt decisions within the governing bodies of the ESOs on topics concerning standardisation requests issued by the Commission and related European standards and European standardisation deliverables.

The **activities** governed by this Regulation (recognised as inputs in the intervention logic in Section 2.1.3) 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.
- **Activities to enhance stakeholder participation and inclusion** (Articles 5 to 7). 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 multi-annual framework programmes under Article 182 TFEU. NSBs are required to encourage and facilitate the access of SMEs to standards and standards development

processes, by implementing specific tasks (as per Article 6 (1)). Furthermore, they are required to (i) exchange best practices on how to enhance SMEs participation (as per 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). This includes a requirement 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). The EU budget finances the ESOs and the so-called 'Annex III organisations', stakeholder organisations meeting the criteria listed in Annex III of the Regulation, through grants. 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).

The **key steps** for developing harmonised standards are the following:

1. **Strategic Planning and 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 in the AUWP, the Commission issues standardisation requests to the ESOs for the development of harmonised standards.

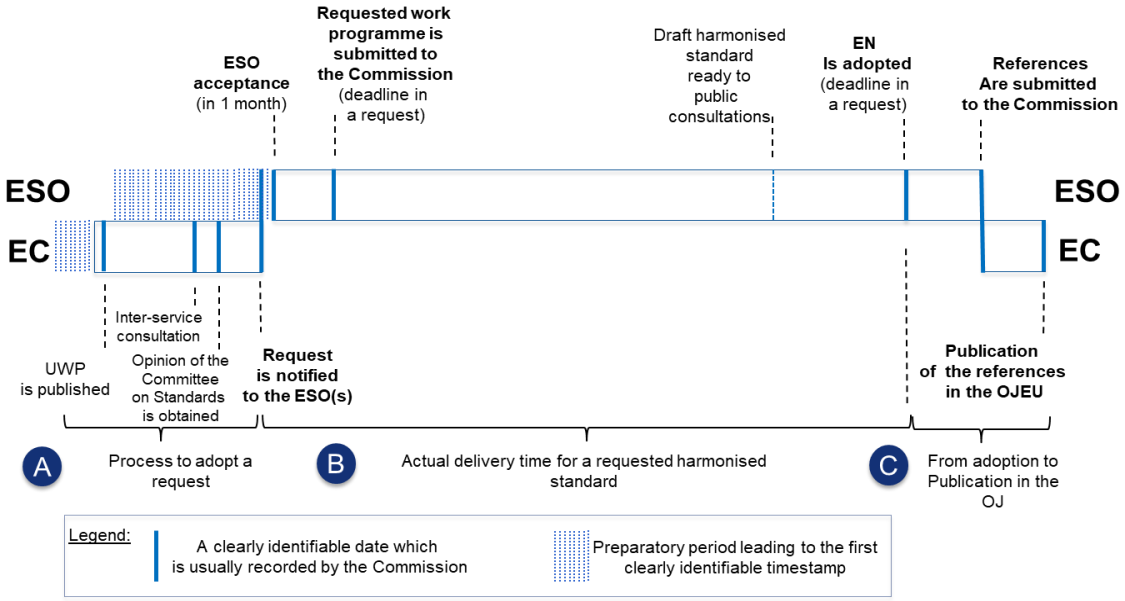
3. **Acceptance of the Request**: The relevant ESO (or ESOs) evaluates and accepts the request, committing to developing the standard within a certain timeframe.

Steps 4 to 8 are not explicitly defined in the regulation as they mainly concern the internal procedures of the ESOs, but are included to provide the full picture.

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 the preparation and drafting of 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 commenting. 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**: Upon successful voting, the standard is adopted as a European Standard (EN) and published. The NSBs must then adopt 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.
9. **Publication in the Official Journal of the EU**: The Commission must assess the compliance of each adopted harmonised standard, and if it meets the requirements, it must publish its reference in the Official Journal (to provide a presumption of conformity or other legal effect depending on which EU legislation is concerned).
10. **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.

In this evaluation, these steps have been divided into three phases: (A) adoption and notification of the standardisation request (step 2 above), (B) drafting and delivery of the standard (steps 3 to 7 above) and (C) submission and publication (step 9 above) (see Figure below). Steps 1 (planning) and 10 (maintenance) are not counted in the calculation of the average duration of the process to develop a harmonised standard.

Figure: Overview of the implementation of the process for the production and citation of harmonised standards, including the role of the European Commission (EC) and European Standardisation Organisations (ESO)



Source: Vademecum on European standardisation in support of Union legislation and policies[297]

[297] SWD(2015) 205 final Part 2, 27 October 2015

ANNEX IX: BACKGROUND INFORMATION – RELEVANT JURISPRUDENCE ADDRESSING PROVISIONS OF REGULATION (EU) 1025/2012

I. Case C-613/14 James Elliot Construction Ltd v Irish Asphalt Ltd

First landmark ruling of the CJEU concerning harmonised standards was delivered in the case C-613/14 James Elliott Construction Ltd v Irish Asphalt Ltd on 27 October 2016. The case was referred to the ECJ by the Irish Supreme court for a preliminary ruling, requiring the Court to provide guidance on the relevant EU law, under Art. 267 TFEU. At national level, the construction company James Elliott Construction Ltd sought compensation from the cement aggregate supplier Irish Asphalt Ltd in the Irish Supreme Court, as the supply caused damage to a construction. The plaintiff alleged that the supplied products did not comply with the Irish transposition standard EN 13242:2002, harmonised with the Construction Products Directive 89/106/EEC, and published in the Official Journal of the European Union. The Irish Supreme Court referred specific questions to the ECJ 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 ECJ, 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, met the necessary requirements under EU law.

Some of the key findings of the Court in James Elliott ruling have a systemic importance, as follows:

1. **Harmonised standards are part of EU law**
    - Harmonised standards, developed by European standardisation bodies under a mandate from the European Commission, are part of EU law.
    - While these standards are voluntary, compliance with them provides a presumption of conformity with the essential requirements of EU secondary sectorial legislation. This gives harmonised standards a legal effect in EU acquis.
2. **Jurisdiction of the ECJ**
    - The ECJ 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 ECJ 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.

<u>Impacts of the ruling</u>

The ruling confirmed the legal significance of harmonised standards and their integration into the EU legal framework. The ECJ determined that harmonised standards, developed by European standardisation organisations under mandates from the European

Commission, are considered part of EU law. This implies that the ECJ 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 the presumption of conformity.

The James Elliott 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 bears the attributes of law development, such as transparency, consistency, and legal certainty in the development and application of harmonised standards.

The key impacts 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 European Court of Justice.
- Commission´s responsibility for legal certainty: The Commission is to ensure that harmonised standards are procedurally developed according to underlying 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 sectorial legislation.

4. Commission´s central role in standards´ development

- The ruling highlighted 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 effectively integrate 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 Art. 10 and 11 of the Regulation (EU) 1025/2012. Those articles relate to the *ex ante*, *ex durante* and *ex post* phases of the

development of harmonised standards and Commission plays a central role. The Commission did not amend the regulation and opted to enhance the standards development process 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 in the publication method of citation/referencing of harmonised standards in the Official Journal of the European Union. Whereas previously, harmonised standards were cited in the C series (Communication), today they are referenced in the L series (Legislation) of the Official Journal of the European Union.

II. 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 the case T-474/15 Global Garden Products Italy SpA (GGP Italy) v European Commission on 26 January 2017. The Global Garden Products Italy SpA requested the cancellation of the withdrawal of a lawn mower from the market, as decided by the European Commission upon reporting the state of Latvia due to the alleged non-compliance with the harmonised standard EN 60335-2-77:2010.

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 2006/42/EC version of the Machinery Directive, after its revision. The harmonised standard EN 60335-2-77:2010 was published in the Official Journal of the EU in April 2011, but the Commission never set an expiry date for the previous harmonised standard of 2006, and which had been officially withdrawn on 1 September 2013.

The issue at stake was thus the validity and legal effect of a harmonised standard which was revised but not withdrawn. More specifically, the question in the case was whether the 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 ECJ 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 in the Global Garden Products Italy SpA ruling were:

1. Legal certainty and harmonised standards:

The Court 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 Court held that the Commission has the power granted by the Regulation (EU) 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 the 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 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 Application of Standards:

The ruling underscores the necessity 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 market placement. Such consistency is vital to provide legal clarity and stability for economic operators.

Steps taken by the Commission following the ruling

The Court recognised the exclusive power assigned by the Regulation 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 terminate it via an explicit repeal of such legal effect. Because of this ruling, the Commission modified the practice by which it publishes the lists of harmonised standards under the specific legal acts.

III. Case C630/16 Anstar Oy v Turvallisuus- ja kemikaalivirasto (Tukes)

The ruling of the CJEU on harmonised standards was delivered in the Anstar case C-630/16 on 14 December 2017. The case was referred to the ECJ by the Finnish Administrative Court, Helsinki (Helsingin hallinto-oikeus) for a preliminary ruling, requiring the Court to provide guidance on the relevant EU law, under Art. 267 TFEU. The Court clarified the role of Standardisation Requests (formerly known as 'mandates') in relation to the legal effect to the related harmonised standards.

The CJEU stated that "It 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 Court concluded that "It follows that the scope of a harmonised standard cannot be interpreted more broadly than that of the mandate on which it is based".

IV. Case C-160/20 *Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport*

The ruling of the CJEU (Grand Chamber) on harmonised standards was delivered in the case C-160/20 Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport case on 22 February 2022. The case was referred to

the ECJ by the District Court, Rotterdam for a preliminary ruling, requiring the Court to provide guidance on the relevant EU law, under Art. 267 TFEU.

The case at national level concerned a youth prevention smoking foundation, the Stichting Rookpreventie Jeugd (Youth Smoking Prevention Foundation, Netherlands) and Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit). 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 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. At the court proceedings, the plaintiffs submitted that Article 4(1) of Directive 2014/40 (2) 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 Court of Justice for a preliminary ruling concerning, inter alia, on 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 in the Stichting ruling

1. Direct references to ISO standards in EU law

The Court (Grand chamber) clarified that it is in the discretion of the EU legislators to make standards mandatory via a reference to 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 Court added 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", thus excluding the possibility to make generic references to standards in EU law.

2. Principle of legal certainty and transparency

The Court analysed the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency. It points out that, whilst that provision refers to ISO standards which have not been published in the Official Journal, 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 European institutions.

Furthermore, the Court held that while imposing obligations to legal entities (companies) via 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 the light of the principle of legal certainty, the Court states that the EU legislature, in the light of the broad discretion that it has in the exercise of the powers conferred on it where its action involves political, economic and social choices and where

it is called on to undertake 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 Court 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 Court 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 Official Journal, the mere fact that that 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 Court states that, in accordance with the principle of legal certainty, such standards 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. In the absence of publication in the Official Journal 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 Court states that, in so far 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 ECJ 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 Commission to assess direct referencing of third party standards, such as those from ISO, into EU legislation, were secondary sectoral legislation imposes legal obligations on individuals.

V. Case C-588/21 P Public.Resource.Org and Right to Know v Commission and Others

The most recent ruling of the CJEU (Grand Chamber) on harmonised standards has been the one in the Public.Resource.Org case C-588/21 P of 5 March 2024. The ruling concerned an access to documents request submitted under Regulation 1049/2001 regarding public access to documents of the EU institutions. Two transparency NGOs ("Public.Resource.Org" and "Right to Know") submitted an access to documents request requesting texts of four harmonised standards. The Commission refused access and the two NGOs appealed the Commission decision to deny the access to documents request and brought the Commission to court (Case T-185/19). In a first instance ruling, the General Court ruled on 14 July 2021 in favour of the Commission, stating that there was no overriding public interest in making the standards freely accessible and that the IPRs of the ESOs were protected under the Treaties. The NGOs launched an appeal. The Grand chamber of the European Court of Justice held that the Commission erred in not disclosing access to four harmonised standards under the Access to Documents Regulation and established the overriding public interest in disclosure as prevailing over the commercial interest of a third party.

The key findings of the Court

1. Harmonised standards are part of EU law

The Court reminded that pursuant to Regulation 1049/2001, the institutions can 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 Court then recalled that it had already held in previous rulings 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 Court 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 European Union, and that individuals must be able to ascertain unequivocally what their rights and obligations are. That free 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 of such legislation. In those circumstances, the Court finds that there is an overriding public interest in the disclosure of the requested harmonised standards. Hence, the Court 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 Court thus ordered the Commission to disclose the relevant harmonised standards.

Impacts 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 Court 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 Court 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 (EC) No 1049/2001.

As regards harmonised standards adopted by the European Standardisation Organisations CEN and CENELEC: the harmonised standards, which had been disclosed under Regulation (EC) No 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: The harmonised standards and any other standards and other deliverable adopted by ETSI are available on the ETSI website.

ANNEX X: BACKGROUND INFORMATION – 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 organisation 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 directly reference standards (not only European ones) in secondary legislation (this process is not regulated by Regulation (EU) No 1025/2012).	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. ▪ Private Standards: This includes association/group standards (adopted by academies, associations, chambers of commerce, and federations) and enterprise standards	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. In a new Japanese law from 2018, any Japanese standards organisation can ask JISC to be accredited to prepare national JIS standards.

	European Union	United States	China	Japan
			(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.	
Main actors	European standardisation organisations CEN, CENELEC and ETSI; national standardisation bodies. Industry-driven consortia also exist, but are not defined in the EU Standardisation Regulation and only play a role in the Regulation in the context of ICT specifications.	Hundreds of stakeholder driven standards-development organisations. The American National standards institution (ANSI) is an umbrella 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).	<u>Government-developed standards</u>: • Standardisation Administration of the People's Republic of China (SAC): unified management, supervision and overall coordination of 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	JISC (Japanese Industrial Standards Committee).

	European Union	United States	China	Japan
			opinions and formulation of standards. • Provincial/municipal governments Private standards: associations, industry, individual companies.	
International presentation	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 and IEC, respectively. ITU: national governments, the European Union is observer.	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. ITU: Ministry of Industry and Information Technology (MIIT) represents China.	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.