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Standardisation package

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

1 Introduction

Regulation (EU) No 1025/2012[1] (hereinafter 'the Regulation') provides the legal framework for allowing the Commission to request European Standardisation Organisations (ESOs)[2] to draft standards and standardisation deliverables for goods and services in support of EU policies and EU law, for EU support to the functioning of the European standardisation system (ESS) and sets out key criteria for the functioning of the ESS.

Under Article 24(3) of the Regulation, the Commission shall report on its implementation every five years. A first report was published in 2016, covering the period 2013 – 2015[3]. This report mainly covers the period 2016-2020, with limitations that some data were only available until 2019, but, where possible, includes also updated facts and figures until 2021. Articles 24(1) and (2) of the Regulation require the ESOs and other organisations that receive EU financing to submit annual reports on their activities. These reports have been taken into account in preparing this report. In support of data collection, an independent study[4] was commissioned.

2 Implementation of the Regulation

The Commission launched a number of initiatives and measures to support the implementation of the Regulation. In support of the 2015 Single Market Strategy[5] and as part of the 2016 Standardisation Package[6], the Commission launched a Joint Initiative on Standardisation (JIS). In a multi-stakeholder and partnership approach, this initiative aimed to modernise the ESS, to maintain its attractiveness, effectiveness and efficiency. The initiative was broken down into 15 different sub-measures, and documents are publicly available[7]. A state-of-play was provided in January 2018[8]. Taking into account also these initiatives and actions, the current implementation of the Regulation can be summarised as follows.

2.1 Transparency between standardisation bodies (Article 4)

Article 4 of the Regulation sets out requirements regarding the transparency of standards between the ESOs and the national standardisation bodies (NSBs), and between these entities and the Commission.

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[1] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJ L 316, 14.11.2012, p. 12.

[2] The three European standardisation organisations within the meaning of the Regulation are the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI).

[3] COM(2016) 212 final.

[4] Study on the implementation of the Regulation (EU) No. 1025/2012 (Article 24) https://doi.org/10.2873/504681 and https://doi.org/10.2873/593923

[5] COM(2015) 550 final

[6] COM(2016) 358 final

[7] https://ec.europa.eu/growth/single-market/european-standards/notification-system_en#jis

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018SC0015

Online tools have facilitated access to draft standards and transparency of standards to the other ESOs, NSBs and the Commission, as required by Article 4. The access to draft standards and transparency of standards, under Article 4 of the Regulation at European level, has been facilitated by the online tools implemented by the ESOs in 2015, as they introduced a mechanism that gives ESO members/participating stakeholders, the Commission and the European Free Trade Association (EFTA) direct online access to the draft European standards and standardisation deliverables. As regards NSBs, in 2019, approximately 70% had online tools facilitating access to draft national standards to relevant stakeholders. Nevertheless, based on the reporting from civil society organisations and small and medium enterprises (SMEs), access to NSB activities remains a challenge.

2.1.1 Guidance

As an additional task to promote transparency, in 2015, the Commission, in cooperation with the ESOs, prepared a **Vademecum**[9] providing guidance to ESOs' representatives, Commission officials, EU Member States and stakeholders on the role of standardisation requests from the Commission[10], how to prepare and adopt standardisation requests[11] and how to execute them[12]. In 2016[13], the Commission also issued a general **checklist** for the **ESOs' to carry out a self-assessment** when preparing and delivering HENs in support of EU law, so to promote the quality of standards and deliverables and successful citation in the OJEU. In some cases[14], for certain policy fields, the checklist was adapted to the specificities of the pieces of legislation and other sectoral requirements.

As part of the Commission's comprehensive guidance on the implementation of EU product rules, the **"Blue Guide"**[15] includes a specific section on standards (Section 4.1.2 and Annex VI)**.**

2.2 Inclusiveness and stakeholders' participation, including research bodies (Articles 5 and 9)

Article 5 of the Regulation requires the ESOs to encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations, and environmental and societal stakeholders in their standardisation activities. The identified stakeholder organisations currently receiving EU financing (also known as the 'Annex III organisations') are Small Business Standards (SBS), the European consumer voice in standardisation (ANEC), the Environmental Coalition on Standards European Environmental Citizens Organisation for Standardisation (ECOS) and the European Trade Union Confederation (ETUC), respectively representing SMEs, consumers, environmental and workers' interests.

[9] SWD(2015) 205 final of 27/10/2015
[10] https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations
[11] https://ec.europa.eu/docsroom/documents/13508/attachments/1/translations
[12] https://ec.europa.eu/docsroom/documents/13509/attachments/1/translations
[13] Ares(2016)6548298 of 22/11/2016
[14] e.g. Directives 2014/30/EU and 2014/53/EU
[15] https://ec.europa.eu/growth/single-market/goods/building-blocks_en#blue-guide

At **European level** (Article 5(1) of the Regulation), Annex III organisations are eligible to participate at policy level in the governance bodies of all ESOs and at the technical level in the technical bodies of CEN-CENELEC and the technical committees of ETSI. Since the last report, new initiatives have been taken to further improve their inclusion and effective participation.

In 2017, CEN and CENELEC implemented a change through which non-industrial Annex III organisations (ANEC, ETUC and ECOS) can submit formal opinions on draft standards (the so-called "right of opinion"). If there is a non-favourable opinion, the technical committee responsible for drafting the standard in question shall consider the justification provided for the opinion and provide feedback. It may also lead to revisions of the draft standard. Overall, 76% of all the formal opinions provided by the societal stakeholders were favourable.

In 2017, ETSI launched a '3SI programme' to engage with Annex III organisations. This programme includes roundtables with ETSI officials and a representative of the stakeholders within ETSI (the '3SI Advocate') to discuss inclusiveness issues. ETSI has not introduced any mechanisms similar to those of CEN and CENELEC for giving non-industrial Annex III organisations a more structural role in the standards development process, such as a formal right of opinion. SBS dissatisfaction with ETSI's inclusiveness was expressed in summer 2021 in the public consultation on the roadmap[16] for a future Commission standardisation strategy, commenting that "*ETSI has so far not dedicated sufficient resources and budgets to increase its inclusiveness*"[17], as echoed by another SME association[18]. Similar opinions have been transmitted in the relevant Article 24 reporting by other organisations financed under the Regulation. For instance, ANEC's report for 2019[19] quotes: "*ETSI is reluctant to deepen its provisions on inclusiveness, believing itself to be in conformity to the Regulation. However, Annex III organisations believe ETSI not to be in conformity*". Similarly, ECOS states[20]: "*Annex III participation in ETSI remains more complex compared to the other two ESOs".* One of their points is that the inclusiveness of the process cannot be separated from voting rights, because in ETSI, the voting rights of industrial stakeholders are higher than the combined voting rights of any other category of stakeholders or Authority. The share of ETSI voting rights from NSBs coming from EU Member States is at circa 2%. The voting rights from other non-industrial stakeholders (civil society, academia, research), this is barely countable in case of a vote.

These concerns have been echoed by certain categories of stakeholders, particularly in the case of accessibility, where some representatives of people with disabilities struggled to perceive the process as inclusive and had to rely on liaisons with consumers' associations. While, strictly speaking, such liaison through consumers' associations is not against the

[16] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy_en.
[17] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy/F2665680_en
[18] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-Strategy/F2665677_en
[19] https://ec.europa.eu/docsroom/documents/44748
[20] https://ec.europa.eu/docsroom/documents/44749

Regulation, the concerns of different categories of stakeholders question whether sufficient attention is being reserved to inclusiveness..

2.2.1 Research bodies

With respect to the implementation of Articles 5(2) and 9 of the Regulation, the reports of the ESOs[21] highlight that there were different activities involving research organisations. However, the reports are not fully clear on the effectiveness of the activities, e.g. on its effects on the adoption of specific standards or increased participation.

In a related development, in October 2016, and as renewed in October 2021[22], CEN, CENELEC and the Joint Research Centre of the European Commission (JRC) signed a cooperation agreement to bridge research and innovation with standardisation, to help to anticipate standardisation needs and to align on strategic priorities.

The JRC also engaged with the COST Association through the JIS in informing and training on the benefits of standardisation to the research and innovation carried out in COST Projects. Through this link CEN-CENELEC provided several training modules since 2019.

2.2.2 ICT tools

The ESOs reported on investment and the use of ICT tools to enhance the efficiency of the ESS and facilitate standardisation activities (such as cooperation between members, meetings, drafting work, accessing working documents and standardisation deliverables, and remote communication and approvals).

2.3 Cooperation between NSBs and ESOs

The NSBs and the ESOs have put mechanisms in place to facilitate exchanges of best practices, such as advisory groups, monitoring committees, meetings and guidelines. The three ESOs use a number of tools to facilitate and improve the exchange of best practices among each other and between national delegations (such as through the heads of national delegations meetings held by ETSI). The ESOs also cooperate on activities including education, training, and research and development in different standardisation related areas, such as joint training activities on standardisation carried out by CEN-CENELEC.

In late 2021, some NSBs voiced concerns about their role within ETSI. There are ongoing discussions between ETSI and some European NSBs about their recognition as strategic partners to standardisation.

2.4 Access of SMEs to standards (Article 6)

Under Article 6(3) of the Regulation, NSBs shall prepare an annual report on their activities to encourage and facilitate the access of SMEs to standards and the standard development procedures. This also includes reporting on the exchange of best practices aimed to enhance

[21] https://ec.europa.eu/growth/single-market/european-standards/notification-system_en#article24
[22] https://www.cencenelec.eu/news-and-events/news/2021/pressrelease/2021-10-21-jrc-cen-cenelec-renewed-cooperation/

SME participation (i.e. Article 6(2) of the Regulation). The study supporting this report has precise statistics on this subject[23], and shows the number of NSBs that allow the related category of stakeholders to be represented , as per the table below. For instance, the first value of the table (29/33) indicates that 29 NSBs allowed SMEs to be represented in CEN, out of the 33 that were associated to that ESO.

Stakeholders / ESO / year	CEN				CENELEC				ETSI			
	2016	2017	2018	2019	2016	2017	2018	2019	2016	2017	2018	2019
SMEs	29/33	30/34	31/34	31/34	29/33	30/34	31/34	31/34	28/39	29/39	29/39	30/39
Consumers	25/33	24/34	25/34	25/34	20/33	20/34	22/34	22/34	26/39	27/39	27/39	27/39
Environmental stakeholders	24/33	24/34	26/34	26/34	18/33	20/34	23/34	23/34	22/39	23/39	23/39	23/39
Social stakeholders	21/33	20/34	23/34	22/34	17/33	18/34	20/34	20/34	19/39	20/39	20/39	20/39

It is worth noting that in some cases the total number of associated NSBs is much higher than the number of EU and EEA Countries. This is because ESOs include non-EU and non-EEA NSBs in their development processes.

One striking piece of information coming in the study is that NSBs in CEN and CENELEC "*have been granting more and more special rates to SMEs for participating in standardisation activities between 2015 and 2019, while ETSI NSBs faced a decreasing trend in such special rates provided".* On this matter, the 2019 ETSI report [24] also reads: *"ETSI does not operate under the national delegation principle so their [SMEs] participation in ETSI's technical organisation and work is direct through their membership of ETSI […]. Only during the public approval process do these stakeholders need to submit their comments via the ETSI NSBs*".

2.5 Participation of Public Authorities in European Standardisation (Article 7)

For the implementation of Article 7 of the Regulation, there is little systematic and official information in the reports to the Commission on the involvement of Public Authorities in standardisation activities. Reports from the ESOs[25] typically refer to actions 4 and 9 of the JIS[26] as suitable exercises. As precise data are not available, a monitoring instrument may be considered in the future.

[23] https://doi.org/10.2873/504681
[24] https://ec.europa.eu/docsroom/documents/44751
[25] https://ec.europa.eu/growth/single-market/european-standards/notification-system_en#annual
[26] Action 4: Improvement of standardisation awareness in national public authorities; Action 9: Inclusiveness, transparency & effective participation of all stakeholders in the European Standardisation System;

2.6 Annual Union Work Programmes (Article 8)

In accordance with Article 8, the Commission has adopted Annual Union Work Programmes (AUWP) for European standardisation[27]. With the AUWP, the Commission gives the ESOs an orientation to work on standards and standardisation deliverables and also how to strengthen the involvement of small and medium-sized enterprises and societal stakeholders in the process. This document has been progressively shaped to provide prioritisation with regard to EU policies as to provide a sense of orientation and expectation from the policy-maker perspective, and also providing better guidance to the standardisation stakeholders in terms of delivery.

2.7 Standardisation requests (Article 10)

In 2015-2019, the Commission issued 35 SRs, with an additional nine in 2020. Out of these 44 SRs, six were rejected (13.6%). The ESOs have often reported the following reasons for rejecting: disagreement on certain requested standards; disagreement on some requirements contained in the SR; disagreement that certain requested technical specifications are needed in support of a specific essential requirement; or disagreement with deadlines set for the delivery of requested standards.

The rejection of SRs can have significant impacts on the (i) implementation of a fair and effective Internal Market; (ii) competitiveness of industries; (iii) participation of societal stakeholders; and (iv) technological sovereignty of the Union. It may also lead to relying on non-EU standards, where it may not be clear to which extent an inclusive process has been followed.

On the execution of SRs, it has also happened that, despite the acceptance by CEN of a SR, only a part of it was implemented[28].

2.7.1 Commission support to the execution of the standardisation requests (HAS)

Before 2018, there was a service contract ("New Approach Consultants" – NACs) to help the ESOs verify the compliance of draft HENs with the Commission's request. Under that contract, the success rate of standardisation deliverables cited in the OJEU was limited and a substantial backlog in non-cited standards accumulated. In March 2017, the Commission internal database listed 596 unprocessed HENs submitted by the ESOs. In order to have an effective service for the implementation of the Regulation, the Commission called for a new service contract[29] ("HAS"). In implementing the new system, the Commission paid attention to resolve some identified problems of the past and to ensure the:

- voluntary nature of the service for the ESOs, also in line with the previous NAC scheme;

[27] https://ec.europa.eu/growth/single-market/european-standards/notification-system_en#annual
[28] in the case of the Marine Equipment Directive 2014/90/EU, despite the acceptance by CEN of the SR M/557, the responsible Technical Committee has not progressed with its implementation, as far as hoses were concerned.
[29] https://ec.europa.eu/growth/content/technical-assistance-area-harmonised-standards_en

- clear separation of roles – consultants do not draft or negotiate the content of HENs, they focus on assessing whether HENs satisfy the requirements of EU law;
- availability of sectoral services to guide on new doubts, questions or issues that may occur in drafting HENs; and
- role of the Commission for the final decision to cite HENs in the OJEU.

The Commission structured the work of the HAS consultants in a manner that would not delay the production of HENs.

Since the operation of the HAS consultants system, as of December 2021, the backlog of non-assessed and processed HENs submitted by the ESOs for citation in the OJEU has been reduced to only two standards from 2018 and five from 2019, which are currently pending a Commission decision.

As of 9 December 2021, the Commissions' contractor managing the HAS consultants, has received 3312 requests for assessments of draft HENs from the ESOs, under 21 pieces of EU legislation, of which 2944 have been processed and 368 were non-eligible[30]. Across all sectors, only 27,58% of the HAS assessments came out as positive[31], mainly due to inadequacy with EU law, showing that more work is to be invested in the development process of standards – e.g. within the technical committees – so that the work is more aligned with the policy and legal requirements.

2.7.2 Production and citation of HENs

In 2016 and 2017, stakeholders had been raising the issue of delayed citations of certain HENs. As a result, the Commission has been monitoring the different stages of the process as of 2018 and the related results are herein reported also for the year 2020.

In 2018-2020, the Commission received **1247 HENs** in support of EU legislation. Of these, **238** were resubmissions of existing HENs under new Regulations. Therefore, the newly submitted standards were **1009,** including **76** corrigenda and **267** amendments.

In the following analysis, this report focuses on the new submissions, which were distributed per year and per ESO as follows:

Delivered HENs	2018	2019	2020	Total
CEN	231	216	129	576
CENELEC	134	161	104	399
ETSI	8	11	15	34
Total	373	388	248	1009

By 9 December 2021, **576** HENs have been cited in the OJEU, **17** are in the process of being cited, **371** have not been accepted and **45** are pending decision.

[30] e.g. because not relating to HENs or because of redundant requests

[31] Note: a single standard is assessed from 2 to 4 times, and each time is counted separately in this statistics. The shown number is therefore not indicative of the negative assessments that appear at a late stage.

Based on Commission internal databases, which interacts with the ESO's IT-tools, the median time between the adoption of a HEN by CEN, CENELEC or ETSI, and the formal delivery to the Commission for citation in the OJEU is 100 days. This means that the ESOs may take over three months to submit, to the Commission, a standard after it was made publicly available (i.e. available for purchase), before the Commission can start assessing and processing the HEN for citation in the OJEU[32]. The average time (in brackets in the table below) is much higher, due to some extreme cases[33].

Median (and average) time (days) between ESO's adoption and delivery to the Commission	2018	2019	2020	Total
CEN	75 (115)	105 (199)	70 (91)	83 (141)
CENELEC	218 (424)	189 (1374)	82 (481)	186 (822)
ETSI	29 (27)	49 (58)	20 (29)	28 (38)
Total	109 (224)	117 (683)	75 (251)	100 (407)

With respect to the processing of HENs by the Commission itself, the median (average) time from delivery by the ESOs to the Commission to citation in the OJEU[34] has steadily decreased, as per table below. The longer processing time needed by the Commission in 2019 was due to the change of publication method (from the C-series of the OJEU to the L-series of the OJEU), which required a transitional adaptation period. Since then, the Commission has substantially reduced the duration of its own processes. In 2020 and 2021, the Commission performed better than in 2018 (when citation of HENs in the OJEU was still done under the procedures for the publication in the C-series of the OJEU).

	2018	2019	2020	2021
Median (and average) time (days) between delivery to the Commission and citation in the OJEU	238 (298)	292 (322)	228 (231)	108 (121)

2.8 Formal Objections (Article 11)

In 2015-2019, a total of 20 formal objections against specific HENs were presented in accordance to the provisions in Article 11 of the Regulation. Three more were presented in 2020[35]. The average duration of a formal objection (intended as the time between its presentation and resolution) is 1084 days, i.e. 3 years.

[32] The Commission cannot start its own internal processing of HENs until they have been formally delivered by the ESOs to the Commission.
[33] The big discrepancy for CENELEC is due to the bundled submission of certain old standards and related more recent amendments. As some of those old standards dated back to the 1990's, the average takes into account delays in the submission, and hence results are biased. In particular, most standards leading to these big delays can be ring-fenced to deliverables under Commission standardisation requests of the Ecodesign legislation.
[34] This covers the whole time needed by the Commission to first evaluate the HENs received from the ESOs and then carry out the internal procedure leading to citation of the HENs in the OJ.
[35] https://ec.europa.eu/growth/single-market/european-standards/notification-system_en#objections

2.9 Notification of stakeholder organisations (Article 12)

The Commission has established a dedicated webpage[36] for the notifications referred to in Article 12.

2.10 ICT specifications (Articles 13 and 14)

Many of the most common ICT technical specifications have been produced lately by private forums and consortia. Article 13 of the Regulation allows the Commission to identify ICT technical specifications to be eligible for referencing in public procurement. This allows for more competition in the field and reduces the risk of lock-in to proprietary systems. A suitable list has been published on the Commission website[37].

In addition, having common ICT standards ensures interoperability. This has become increasingly important as many more devices are being connected to each other. With the Communication on ICT Standardisation Priorities[38] of 2016, the Commission has proposed to focus standard-setting resources and communities on five priority areas. The importance of ICT standards was stressed again in the Industrial Strategy of 2020[39].

A European Multi-Stakeholder Platform on ICT Standardisation[40] has been set up to advice the Commission on matters relating to the implementation of ICT standardisation policy, including priority-setting, and the identification of specifications. More than 150 actions were identified and grouped into thematic areas.

3 Financing the ESS (Article 15, 16 and 17)

The EU financing to the ESOs and the Annex III organisations for activities is defined under Articles 15, 16 and 17 of the Regulation.

In 2015-2019, the grants for standardisation activities from the EU totalled around EUR 105.3 million (EUR 85 million allocated to the ESOs and EUR 20 million to the Annex III organisations). EU and EFTA co-finance part of the organisations' costs and activities. The grants are provided in the form of operating and action grants. The operating grants contribute to the operating budget to carry out annual work programmes, which specify the planned activities for each year, in line with the Commission's standardisation objectives. The operating grants for the period 2015-2019 covered a broad range of everyday activities. The action grants financed specific activities in support of EU legislation and policies. In 2019, action grants made up 66% of EU financing to the ESOs and Annex III organisations. The Commission follows up on the execution of the funded activities via reporting from the ESOs.

[36] https://ec.europa.eu/growth/single-market/european-standards/notification-system_en
[37] https://ec.europa.eu/growth/single-market/european-standards/ict-standardisation/ict-technical-specifications_en
[38] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016DC0176
[39] https://ec.europa.eu/growth/industry/policy_en - industrial-strategy-2020
[40] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=2758

Among the ESOs, CEN has been the main recipient, receiving approximately 71% of the total funding provided to the ESOs in 2015-2019, followed by ETSI (22%) and CENELEC (7%). The overall shares of the total EU funding to the ESOs provided for operating grants and action grants have remained generally stable over the reporting period.

The financial support to the Annex III organisations aims to improve the inclusiveness of their respective interest groups in the development of standards, and has increased overall in the last 5 years. SBS and ANEC have received the largest shares (42.5% and 34.5%, respectively) of the total EU financing provided to Annex III organisations between 2015 and 2019. ECOS received 15.7% of the total financing and ETUC 7.3%.

Regarding the simplification of the financing of the ESS and the reduction of the administrative burden, in 2015, the Commission introduced a lump-sum mechanism for financing certain costs within their grant agreements, such as person-days required or travel costs incurred. This mechanism helped reduce the administrative burden of having to justify and record each individual case of such costs. However, an analysis revealed that beneficiaries continued to have uncertainties regarding the records required for potential audits.

As regards reporting requirements, the stakeholders perceive some of these reporting activities as burdensome. The drafting of action plans and reports for the operating grant are the most time-consuming tasks, with a slight increase in the required person-days since 2015. However, while the reported data from the ESOs show an increase in the average time needed to draft proposals for action grants, they show a decreased average time for the reporting on action grants.

4 Conclusions

This second report to the European Parliament and Council on the implementation of Regulation (EU) No 1025/2012 shows that the European standardisation system improved in some aspects – e.g. with regard to new IT tools – but that there is room for improvement in different areas. This applies in particular to aspects of inclusiveness, the role of NSBs in the ESS and the delivery time of HENs to the Commission, as illustrated above.

As regards the time for processing standards and standardisation deliverables, both the ESOs and the Commission must continue improving their efforts to increase the efficacy despite the Commission’s recent efforts to substantially reduce its adoption time for the publication of the HENs.