

FIT FOR FUTURE Platform Opinion

Topic title	The functioning of European standardisation regulation
	AWP 2023
	Regulation 1025/2012 on European standardisation <i>Legal reference</i>
Date of adoption	28 November 2023
Opinion reference	2023/4
Policy cycle reference	<input type="checkbox"/> Contribution to ongoing legislative process <i>Commission work programme reference</i>
	<input checked="" type="checkbox"/> Contribution to the (ongoing) evaluation process Evaluation of the functioning of European standardisation regulation with regard to the new developments and challenges facing European standardisation <i>Title of the (ongoing) evaluation</i> Regulation 1025/2012 on European standardisation provides for a comprehensive legal framework to support the EU's standardisation policy. Since its adoption in October 2012, the standardisation environment has substantially changed. The evaluation of the regulation was announced in the EU Strategy on Standardisation . The overall objective of the evaluation is to assess whether European standardisation is efficient and effective for current and future needs and the current legal framework is still sufficient to respond to the new opportunities and challenges of globalisation to ensure the safety of EU citizens as well as to support the green and digital transition. It will look at issue such as transparency, involvement of SMEs, civil society and users and access to standards.
	<input type="checkbox"/> Included in Annex VI of the Task force for subsidiarity and proportionality -
	<input type="checkbox"/> Other -

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SUGGESTIONS SUMMARY

- Suggestion 1:** Refrain from a full revision of Regulation 1025/2012
- Suggestion 2:** Ensure consistency with Regulation 1025/2012 across legislation
- Suggestion 3:** Maintain the Market-Based Approach to Regulation 1025/2012
- Suggestion 4:** Establish a formal and independent role for stakeholders for coordination of standardisation activities
- Suggestion 5:** Follow a horizontal approach for the adoption of common specifications
- Suggestion 6:** Reinforce inclusiveness in standardisation at European, national, and international level
- Suggestion 7:** Ensure more researcher participation in standardisation

SHORT DESCRIPTION OF THE LEGISLATION ANALYSED

Standards are at the core of the EU single market. The European standardisation system delivered more than 3 600 harmonised standards over a period of 30 years-as the preferred means - allowing companies to demonstrate compliance with EU law and trade freely - and many more European standards and technical specifications to promote inter-operability, the safety of EU citizens and protection of the environment. Standards created a level-playing field in the single market for businesses and increased consumer confidence.

[Regulation 1025/2012 on European standardisation](#) was adopted in October 2012. It seeks to simplify the legislative framework to reflect the latest developments and future challenges and aims to modernise and improve standardisation, which plays a leading role in the EU's single market by outlining how:

- the EU standards-setting process operates; and
- the various organisations involved in this process (both at EU and national level) work together;
- standards support market competition, reduce costs, improve safety, and enhance competition, protecting health, safety, security and the environment.

The regulation introduces rules governing:

- cooperation between the standardisation organisations of CEN and CENELEC and ETSI national standardisation bodies, EU countries and the European Commission;
- market-driven European standards for products and services in line with EU legislation and policies;
- how information and communication technology technical specifications can support this process;
- financing of standardisation activities, normally in the form of grants or calls for proposals in line with EU legislation and policies;
- stakeholder participation.

The regulation covers standards for products as well as for services and reiterates that harmonisation legislation defines public interest protection objectives.

On 2 February 2022 the Commission published an [EU Strategy on Standardisation](#), proposing a set of actions ensuring that the EU Standardisation System is better geared towards meeting EU priorities, core principles and values, notably the green and digital transition as well as strengthening the global role of the European standardisation system. The actions aim at:

- anticipating, prioritising and addressing standardisation needs in strategic areas;
- improving the governance and integrity of the European standardisation system;
- enhancing European leadership in global standards;
- supporting innovation;
- enabling the next generation of standardisation experts.

The Strategy was accompanied by a proposal for a targeted and technical amendment of Art. 10 of Regulation 1025/2012 to reinforce the European standardisation system and ensure that good governance principles are applied throughout all critical steps in the standardisation development process. Specifically, the proposal reinforces the role of national standardisation bodies (NSBs) of EU Member States¹. This ensures a balanced decision-making process within the European standardisation bodies: the national standardisation bodies conduct local/regional/national consultations with key stakeholders, which brings more inclusiveness to the process. At the same time, giving the decision making to the national standardisation bodies of the Member States and the EEA brings in minimal checks and balances to the system, safeguarding EU interests and objectives in the process. This does not preclude the participation of entities from third countries in the standardisation development processes.

On 14 December 2022, the [amendment to the Regulation](#) was adopted by the Council and the European Parliament. Regulation 2022/2480 was published in the Official Journal of the European Union on 19 December 2022.

Sources:

[Regulation 1025/2012 on European standardisation](#)

[An EU Strategy on Standardisation, Commission communication COM\(2022\)31](#)

[Regulation 2022/2480 of 14 December 2022 amending Regulation 1025/2012 as regards decisions of European standardisation organisations concerning European standards and European standardisation deliverables](#)

¹ It is the more important given that the European Court of Justice clarified in two judgements (Case C-613/14 and Case T-185/19) that harmonised European standards form part of EU law;

PROBLEM DESCRIPTION

Existing evidence collected by the Commission suggest the following issues:

The [2022 EU's Strategy on Standardisation](#) was accompanied by the [Commission report](#) on the implementation of the Regulation 1025/2012 from 2016 to 2020, which reported on several aspects pertaining to REFIT-related aspects.

The ESOs mentioned the link between the standardisation requests and the associated EC funding. The ESOs have one month to respond to the EC standardisation request. Only after preparing their quotation (i.e. request for action grant) and receiving the European Commission's response, they know whether their activity will receive funding. However, in order to guarantee available support from members, the ESOs are required to ask for their members' commitment to work on the requested standard before the decision which is obviously linked to the financial interest that members have in a given standardisation task. The ESOs mention that the acceptance of a standardisation request cannot be conditional to the funding which is seen as a recurring problem for them and their members.

Another related matter was the perceived lack of coordination and timing related to the submission and acceptance of proposals. Despite each ESO operating within a specific range of sectors, there are several areas of standardisation work which require equal attention from all three. The submission of separate proposals could lead to several overlapping activities, hence requiring additional time and effort from the European Commission to thoroughly review the different proposals and ensure that their activities are coherent, which ultimately delays the decision and creates additional administrative pressure. Different timing and delays with regard to proposal submission are also considered as problematic, when the ESO members do not produce the proposals in a consistent manner. It creates the need for repetitive ad-hoc work several times and puts pressure on the budget² and ultimately risks delays. Finally, submitted proposals are perceived as lacking sufficient details and justification for the proposed activities, which are also not always in line with the Annual Union Work Programme.

[Regulation 1025/2012](#) (the 'Regulation') imposes certain reporting obligations. The 2022 implementation report and the accompanying study identified reporting inconsistencies (e.g. inconsistency of data across the annual reports, unharmonized taxonomy of terms and notions hindering comparability and transparency), issues with the use of operating grants for not authorised tasks and administrative burdens. With regard to the latter, according to the ESOs, the lump sum financing mechanism introduced in 2015 by the European Commission has contributed to a decrease in the administrative burden³.

The ESOs and Annex III organisations⁴ noted as well the interim and final report on the operating or action grants they receive as being particularly burdensome to prepare and the details required by the Commission have reportedly grown throughout the years, leading to an

² Evaluation committee must be set up for each proposal and the budget reserved and committed before the end of the year;

³ The new payment system does not require a justification for man-days and travel costs incurred, meaning that there is no direct cause to record timesheets for this type of financing, compared to the timesheets needed for action grants;

⁴ European stakeholder organisations eligible for union financing;

increase in the time needed to complete the reports. The second most burdensome information obligation is the drafting of the action plan for the grant, which is essential to lay out the programme of work for the organisations.

Art. 4 of the regulation sets out requirements regarding the transparency of standards between the European standardisation organisations (ESOs)⁵ and the national standardisation bodies (NSBs), and between these entities and the Commission. Online tools⁶ have facilitated access to draft standards and transparency of standards to the other ESOs, NSBs and the Commission⁷. Nevertheless, based on the reporting from civil society organisations and small and medium enterprises (SMEs), access to NSB activities remains a challenge.

There is little systematic and official information in the reports to the Commission on the involvement of public authorities in standardisation activities, indicating insufficient monitoring. The inclusiveness (including accessibility) and stakeholders' participation, including research bodies, in the ESOs standardisation activities have been broadly meeting the stakeholders expectations as far as CEN and CENELEC are concerned while stakeholders flag complexity and opaqueness of the ETSI processes, including the ETSI voting rights⁸. Under Article 6(3) of the Regulation, NSBs prepare an annual report on their activities to specifically encourage and facilitate the access of SMEs to standards and the standard development procedures. The study and the implementation report hint to a similar conclusion that while the Membership NSOs of 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.

Lastly, some inefficiencies have been identified in the production and citation (in the OJEU) of the harmonised standards. The median time between the adoption of a harmonised standard by the ESOs and the formal delivery to the Commission for citation 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 it for citation in the OJEU. With respect to the processing of a standard by the Commission itself, the median time from delivery by the ESOs to the Commission to citation in the OJEU has steadily decreased, settling at a median time of around 108 days in 2021. Finally, there appears to be some process inefficiencies as regards the development of the standards. As of December 2021, the ESOs submitted 3312 requests for assessments of draft standards under 21 pieces of EU legislation, of which 2944 have been processed and 368 were non-eligible. Across all sectors, only 27,58% of the harmonised standards assessments came

⁵ 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);

⁶ The access to draft standards and transparency of standards 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;

⁷ As regards NSBs, in 2019, approximately 70% had online tools facilitating access to draft national standards to relevant stakeholders;

⁸ 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;

out as positive⁹, mainly due to inadequacy with EU law. At the same time, the assessment and drafting period of a candidate harmonised standard by the European Commission is currently at an average of 186 days with an additional 66 days in average spend in the formal decision process¹⁰.

Sources:

[Commission report](#) on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020

[Study](#) on the implementation of the Regulation (EU) No. 1025/2012 (Article 24), 15/10/2020

SUGGESTIONS

Suggestion 1: Refrain from a full revision of Regulation 1025/2012

Description: It is clear that certain inefficiencies and areas of improvement are needed for how the European Standardisation system works. However, following the Targeted Amendment to [Regulation 1025/2012](#) which addresses specifically issues of governance of the European Standardisation Organisations, we see little need to revise further the Regulation especially in light of the Targeted Amendment, which should be in place for a period of time, prior to reassessing the need for a further revision of the Regulation.

The objective of any evaluation of Regulation 1025/2012 should be on the basis of assessing if standardisation is efficient and effective and that standards needs are carried out in a consistent manner that ensure the measures are proportionate to the needs of all involved stakeholders.

In doing this it is crucial to acknowledge the issues of governance and ‘bottlenecks’ in publication of standards are linked intrinsically together. Many issues in the European Standardisation System 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 - HAS consultants, Standards Bodies, Technical Committee experts, and the Commission. A forum for this dialogue is, for example, the joint Task Force “Task Force on timely delivery of European standards for a green and digital, single and global market” between the Commission and the ESOs.

Expected benefits: Before enacting a revision of the Regulation sufficient time must be given for the ESOs, particularly ETSI, to implement the changes stemming from the Targeted Amendment. Yet a number of the inefficiencies identified in the problem statement above could be solved via guidelines, as opposed to a formal reopening of the Regulation, such as a revision of the vademecum. Such alternatives to hard law solutions would be preferred as the Regulation continues to function and provide a solid base of confidence for the ESS. A revision in this

⁹ Note: a single standard is assessed from 2 to 4 times, and each time is counted separately in the statistics. The shown number is therefore not indicative of the negative assessments that appear at a late stage;

¹⁰ Presentation given by DG GROW in the Committee on standards meeting in May 2023, slide 10 (“overall ÒJ publication time* and duration of its elements in days);

current climate of increasing politicisation of standards as well as the expected ECJ ruling on ‘Right to Know’ would likely lead to prolonged negotiations around the Regulation- de facto undermining legal certainty in the ESS for the foreseeable future as well as our system’s attractiveness to stakeholders.

Suggestion 2: Ensure consistency with Regulation 1025/2012 across legislation

Description: 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 specializes 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. While the first aspect does fall under the realm of financial reporting, the second aspect involves measurements and more technical details that CEN and CENELEC European standards are suited for.

Expected benefits: European companies will have to report against EFRAG ‘European Standards’ and conformity against NLF Harmonized Standards (as governed by Regulation 1025/2012). Ensuring consistency would avoid: unnecessary duplication of work, increased costs, confusion in the market, and redundant reporting. These inconsistencies are particularly prominent in European regulations that rely heavily on standardisation for the development of methodologies to meet legal requirements. For example, EN ISO 14064:2019 series on Greenhouse gases would be an example of harmonized standard that would be directly relevant to sustainability reporting.

Suggestion 3: Maintain the Market-Based Approach to Regulation 1025/2012

Description: 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.

However when conducting optimisation activities as outlined under Suggestion 1 of the various processes stemming from the Regulation, we reiterate that Standardization 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. Thus as outlined in the Vademecum, Standardisation Requests are based on clearly defined public interest and policy objectives, are market driven, and are based on consensus.

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 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.

Expected benefits: Maintaining a market-based, voluntary approach, ensures that standardisation requests meet the actual needs of the market. However while the approach needs to stay market-based, the European system must have checks to ensure that all standards developed are in order with European values. This ensures time, effort, and resources for all stakeholders involved are being utilised effectively and standards that are not needed do not end up being developed. This is particularly important for SMEs who have limited resourcing. Furthermore, allowing for participation of international expertise at a technical level prevents Europe from decoupling from the international standardisation scene. This inclusion should also be extended for the relevant societal and consumer organisations as well.

Suggestion 4: Establish a formal and independent role for stakeholders for coordination of standardisation activities

Description: 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 prioritizing European standardisation efforts.

Expected benefits: Stakeholder representation is crucial for standardisation to reflect the needs of the market - especially for SME and to reflect the societal needs, particularly for societal stakeholders, vital to secure balance for all voices. This will allow for better coordination of strategic priorities set by the forum. Furthermore clarifying the Forum's activities does not necessitate a revision of the Regulation.

Suggestion 5: Follow a horizontal approach for the adoption of common specifications

Description: In its Standardisation Strategy (COM(2022)31), the Commission announced that it would work towards a horizontal approach in terms of criteria and processes for when and under which conditions the Commission could be empowered to develop 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 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.

Yet in the case common specifications are deemed necessary, a common process for their adoption, should consider whether:

1. There is no reference to harmonised standards published in the Official Journal of the European Union according to Regulation (EU) 1025/2012 and no such reference is expected to be published within a reasonable period;

The Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard:

(i) the request has not been accepted, or

(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or

(iii) The European standardisation organisation has delivered a standard that does not comply with the request of the Commission.

2. When references to a harmonised standard are published in the Official Journal of the European Union, the relevant implementing acts that cover the same subject or parts thereof as the published harmonised standard have been repealed;
3. Clear deadlines and time limit are established that detail exactly when a common specification will become valid and when it will be withdrawn;
4. The Commission ensures funding is not diverted from the European standardisation organisations in the pursuit of developing common specifications.

Expected benefits: Having clear conditions and a horizontal approach for adopting Common Specifications will give all stakeholders the legal certainty that future Union legislation will not establish a fragmented legal basis for the adoption of common specifications. In general, having consensus on the adoption of common specifications should then result in better focus on alleviating time for developing standards instead of confusion over when a potential common specification could be issued that results in the creation of a parallel procedure to standardisation.

Suggestion 6: Reinforce inclusiveness in standardisation at European, national, and international level

Description: 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, we must acknowledge that European stakeholder organisations representing consumers, environmental interests, trade unions and SMEs in standardisation confirm that 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.

Additionally some measures that should be considered are:

- Need for the systematic facilitation of Annex III member participation across NSBs at national level
 - Ensure entry-conditions across NSBs/NSOs for Annex III national constituencies are standardised and as barrier-free as possible.
 - Pro-active outreach to national stakeholders for them to engage in standards-making
- Ensure appropriate funding and direct financial support for the participation of SME/Independent experts in the standardisation process via support funds based on regulation 1025/2012 Article 16.
- Ensuring adequate preparation of European ESOs at the international level in order to ensure international standards are in-line with European values and can be adopted as European standard.
- The rights of the Annex III organisations within ESOs must be further reinforced to ensure they not only ‘have access’, but that they can ‘effectively participate’ at national and European level. Noting this work should be carried out by the respective national SME, consumer, social interests, or environmental protection organisations.

Expected benefits: European standards are of vital interest for the competitiveness of SMEs which, however, are in some cases under-represented in standardisation activities. Furthermore, standards can have a broad impact on society, in particular on the safety and well-being of citizens, the efficiency of networks, the environment, workers’ safety and working conditions, accessibility and other public policy fields. Therefore, it is necessary to ensure that the role and the input of societal stakeholders in the development of standards are strengthened, through the reinforced support of organisations representing consumers and environmental and social interests.

Suggestion 7: Ensure more researcher participation in standardisation

Description: 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.

Expected benefits: Positive European initiatives are currently emerging to strengthen this link (STAND4EU, HSBooster, Code of Practice on Standardisation for Researchers, etc.). However, there is still much to be done. European and national actors must help improve this link. 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.

DISSENTING VIEWS

Dissenting opinion by Ursula Pachl (BEUC)

Rationale for dissenting views on the suggestions:

BEUC does not support suggestion 1 as proposed: **Refrain from a full revision of Regulation 1025/2012**

Despite some positive elements in this draft opinion, BEUC cannot agree to it. The main issue remains the first recommendation. This recommendation is not justified, and it is too early to anticipate the scope that such a reform may take. The recommendation aims at precluding a more in-depth reform, which is in BEUC's opinion the wrong approach.

Reason 1)

BEUC considers that a reform of the governance of standardisation is necessary to meet important public policy objectives. This is not to put into question the high relevance of standards to ensure that products placed on the Single Market are safe, sustainable and interoperable. But the rise of "socio-technical" standards and the impact of standards on fundamental rights particularly in the digital environment with technologies like artificial intelligence, have brought new challenges that are currently not appropriately addressed by Regulation 1025/2012. It is for example essential to ensure that it is the democratically legitimised EU legislator that takes the decisions on how fundamental rights are reflected and complied with in secondary legislation, not standardisation bodies. BEUC sees the need for important changes to Regulation 1025/2012 to address inter alia:

- the delineation between what is standardisable and what is not;
- the issue of fundamental rights and how to avoid delegation of policymaking to standard-setting bodies;
- the consequences of the James Elliott judgment, including in terms of scrutiny over draft harmonised standards.

Therefore, we disagree with the first suggestion but also other parts of the draft opinion that refer to the fact that Regulation 1025/2012 should not be revised (Suggestion 4 "expected benefits", Suggestion 6).

Removal of these references and focus on the ongoing evaluation to do the mandated work of the F4F platform, namely, to recommend what the evaluation should address, instead of what should be the outcome or the scope and technique of reform, could have solved this issue.

Reason 2)

Recommending to the European Commission that in any case no bigger revision is desirable - no matter what the forthcoming evaluation, call for evidence or other consultation input and available research would show is not acceptable to BEUC. It would preclude the European Commission's task of evidence finding and the results of a yet to come public consultation. In

BEUC's opinion, it is also not included in the mandate of the F4F platform to recommend a specific the regulatory technique and/or scope of any revision.

Alternative suggestions:

Suggestion 2: A revision of Regulation 1025/2012 should effectively address new challenges of standardisation and current legal uncertainties.