



The Regulation 1025/2012 is a Strong Base for European Standardisation

Feedback on the Public Consultation

1 Assessing Regulation 1025/2012 for Modern Challenges: Perspectives on Standardisation and Digital Transformation

Bitkom is eager to provide insights on regulation 1025/2012's ability to meet modern challenges. By addressing globalisation, public safety, and the green and digital transformation under the legal foundation established by this regulation, the European Standardisation System (ESS) can deliver a powerful and effective contribution to boost the global competitiveness of Europe's industry significantly.

Bitkom is Germany's leading association of the digital industry and our working group on standardisation has a broad and deep level of expertise from the ICT sector on standardisation and standards policies.

Standardisation is crucial for the competitiveness of European industries, especially in global markets. Europe is an export-oriented continent. The success of the German and European industry largely rests on international standards and on having European standards identical to international standards. The [industry is a, and often the leading contributor to standardisation](#). The transparent procedures and consensus model ensure that the interests of all stakeholders are adequately represented, which promotes inclusivity. In general, and as it has already been expressed in a previous position paper¹ on the EU standardisation strategy, Bitkom does not see a necessity for, or any potential merit in revising regulation 1025/2012. However, its implementation needs further improvements based on lessons learned.

The three European standardisation organisations CEN, CENELEC and ETSI collaborate effectively, addressing their respective areas of expertise with precision and efficiency. [Thus far, the challenges that have arisen in the context of regulation 1025/2012 have stemmed from its implementation, rather than from the legal framework itself.](#)

Several of them have been addressed, e.g. in the EC-EFTA-ESO Task Force.² This could be a blueprint for a pragmatic way towards a more effective implementation of EU regulations. The process of generating harmonised standards, from the drafting process of standardisation requests (SReq) to the listing process in the OJEU, should be the reform's main focus.

[Instead of creating unnecessary risks of uncertainty and destabilisation of the solid legal foundation set by regulation 1025/2012, strong efforts should be made on](#)

¹ [Link to the study](#)

² The Action Plan agreed by the Task Force was published by CEN-CENELEC: [Link](#)

[further improving the processes on the level of the implementation of regulation 1025/2012 and addressing the issues.](#)

Bitkom reckons that regulation 1025/2012 is aptly crafted to tackle upcoming standardisation challenges. The regulation provides a solid and proven foundational framework for the ESS, and has the built-in flexibility required to adapt the operation of the system to present and future opportunities and challenges. This includes opportunities and challenges identified in the EU Strategy on Standardisation *vis-à-vis* the aims to strengthen the EU's global competitiveness, enable a resilient, green, and digital economy, and enshrine democratic values in technology applications. As a representative of the digital industry, we are convinced that the provisions and guidelines within this regulation are forward-thinking, making it a cornerstone to address the complexities of digital transformation in the years to come and to ensure a fast delivery of the needed standards for the EU's industry and societies.

2 Improving the Implementation of Regulation 1025/2012

As explained above, we strongly recommend focusing further efforts on urgently needed improvements to the current implementation of regulation 1025/2012, instead of on unnecessary and unmerited changes to the regulation itself. In this section, we offer our perspective on the nature of these issues and provide recommendations on how they could be addressed effectively.

[In a nutshell, the lack of *state-of-the-art* listed hENs hinders easy access to the EU's internal market.](#) To overcome implementation hurdles, Bitkom urges the adoption of new guidelines for SReq, expedited listing of standards in the OJEU, and re-evaluation of restrictive listing practices. These steps are crucial to enhance market access and regulatory efficiency.

Furthermore, Bitkom believes that within the public-private partnership the processes, by which standardisation committees generate standards, must continue to improve. The industry is ready to contribute to improvement.

Standardisation Requests

As per art. 10 of regulation 1025/2012 the COM can request standards from the ESOs. Under art. 12 the COM can issue notifications to the ESOs in form of a "Draft standardisation request" that a SReq will be coming. This has been particularly useful in the case of the AI Act and the Digital Product Passport (DPP), where the prudent use of art. 12 lead to an early discussion of the relevant work. [Bitkom encourages the COM to continue with this good practice.](#) An early assembly of stakeholders will certainly always help the standardisation work.

High-quality and consensus-based standardisation requires a certain timeframe to ensure that the right discussions will happen. As such, the deadlines given by the SReqs should be chosen adequately. When choosing timelines, three phases of the overall time required should be considered:

- (A) preparation time required by an ESO for setting up its work environment, getting all stakeholders engaged, assessing available standards, etc.;
- (B) time required for the development of the standards;
- (C) time required for the implementation of the standards by the industry.

Especially phase (A) may be addressed very early on and can, for example, be done in parallel to the development of the respective SReq. Overall, a minimum of 24 months for phases (B) and (C) seems to be appropriate, also considering all the needs for process steps and consultations under WTO requirements.

SReqs are not standardised. The recent SReq (under art. 10 and 12 will be treated equally) for AI, Cyber Resilience (CR) and the DPP all go into different depths describing the requirements for the requested standards, e.g. the DPP-SReq contains in Annex II, Part B under 1.6 a list of standards that should be “duly considered”, something that is unusual and thus, rightly, does not exist in SReqs for AI and CR.

Lastly, SReqs should be addressed to the most adequate ESOs, which includes ETSI. Bitkom asks the COM to not exclude ETSI of future SReqs.

Listing of Standards in the OJEU

It is a common concern of the stakeholders in standardisation and the COM that appropriate standards are listed promptly as soon as they are finalised. For example, the time for citation is reported by ESOs as being up to and above 300 days after their submission to the EC. This is a significant delay incompatible with Article 10 (6) and a burden for industries. This should be reduced to one month maximum.

Therefore, [procedures that have had a negative effect on the quality, number and speed with which hEN have been listed in the official journal of the EU \(OJEU\) should be re-evaluated](#). For example, the subjectivity of the assessment criteria weakens the principle of consensus, which must be the core principle of the standardisation according to the regulation. Particularly, the definition of state of the art should remain the result of consensus within the standardisation drafting groups (as described in Article 10 (1)), acknowledged by national votes (as described in Article 10 (2a)).

Bitkom suggests an annual workshop with the COM and all stakeholders to discuss the implementation of regulation 1025/2012. Implementation optimisation is a continuous task, as such adaptations should be made step-by-step, aiming for consistent improvement. Moreover, it should address inclusiveness, in particular SME participation, and aim for continuous improvements on this level.

Restrictions to the Presumption of Conformity

The increase in standards cited with restrictions often results in a loss of presumption of conformity (PoC), making them ordinary standards and rendering the extra work

wasted, e.g.: EMC standards for radio products under the RED (2014/53/EU) from the EN 301 489 series (parts -12, -20, -52)³, which do not trigger the presumption of conformity due to the restriction (the problem with the tolerances, which is still not definitively resolved and is blocking all other parts of the series). Bitkom asks the COM to assess the lifting of PoC hampering restrictions and to not employ this tool in the future.

Good Data for Better Decision-Making

To fully realize the benefits of regulation 1025/2012 for ESS, we need to optimise its implementation. The baseline for the assessment of the implementation of regulation 1025/2012 should be evidence-driven. Here three studies stand out:

1. With regards to the assessment of standards publication practice until 2008: COM staff working paper from 2011⁴, in particular the figures on pages 12 and 141;
2. Related to the HAS-Consultant system: EY study for the COM published in 2020⁵, in particular chapter 2.2.2;
3. Related to the time between delivery to the European commission (COM) and citation in the OJEU: COM report from 2022⁶, in particular the analysis on page 8. Although this analysis is missing the distinction between the time required for HAS-Consultant work and COM work.

Bitkom urges the COM to repeat these studies for the timeframe from 2012 to 2023 to ensure comparability of the data. A more complete understanding of these aspects will certainly help to inform the discussion on regulation 1025/2012. The currently available studies simply do not cover a long enough timeframe.

3 A Potential Targeted Amendment to Regulation 1025/2012: European Standards and EU Law

Major uncertainty and implications in the ESS are due to the interpretation of the European Court of Justice that standards form part of the law. This interpretation goes against the basic philosophy of the European regulatory system that has a separation of essential legal requirements laid down in the legal acts, and the possibility of developing hENs outlining one possible way of how to build technology and be

³ [Link to an example of restricted listing](#)

⁴ [Link a study that elaborates, amongst other things, on publication times of hENs pre 1025/2012 on pages 12 and 141](#)

⁵ [Link to a study that assesses HAS-Consultant work from 2018-2019 in chapter 2.2.2](#)

⁶ [Link to a study that assesses the time the COM requires to list hENs in the OJEU on page 8](#)

compliant with the essential legal requirements. The respective harmonised European standards provide a presumption of conformity in the context of market surveillance. This regulatory system has been a cornerstone of the EU single market over the last decades.

To increase clarity and avoid further confusion on this issue the European Commission may consider a targeted amendment of the respective paragraphs in regulation 1025/2012. They led to the Court of Justice's interpretation but had been unintended by the lawmakers. A respective article that could be addressed would be Article 10.

However, legal analysis may show that a clarification of regulation 1025/2012 may not be sufficient but that other legal texts may also have to be amended. This is a further argument for not revising regulation 1025/2012 but addressing this issue in a targeted amendment only. If amending other legal acts is required, this should be done in the same targeted way in an omnibus approach.

Bitkom represents more than 2,200 companies from the digital economy. They generate an annual turnover of 200 billion euros in Germany and employ more than 2 million people. Among the members are 1,000 small and medium-sized businesses, over 500 start-ups and almost all global players. These companies provide services in software, IT, telecommunications or the internet, produce hardware and consumer electronics, work in digital media, create content, operate platforms or are in other ways affiliated with the digital economy. 82 percent of the members' headquarters are in Germany, 8 percent in the rest of the EU and 7 percent in the US. 3 percent are from other regions of the world. Bitkom promotes and drives the digital transformation of the German economy and advocates for citizens to participate in and benefit from digitalisation. At the heart of Bitkom's concerns are ensuring a strong European digital policy and a fully integrated digital single market, as well as making Germany a key driver of digital change in Europe and the world.

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