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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE EVALUATION

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

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On 1 January 2013, [Regulation \(EU\) 1025/2012](#) became applicable, setting out a new legal framework to organise the interface between the European Commission and the broader, privately-run European standardisation system on the delivery of harmonised standards in support of EU policies and legislation. The specific objectives of the Regulation were to reduce the delivery time for standards developed at the Commission's request, to ensure that small and medium-sized enterprises (SMEs) and societal stakeholders were adequately represented in the standardisation process, to broaden the use of information and communication technologies (ICT) standards, and to remove ambiguities in the existing legal framework. To this end, Regulation (EU) 1025/2012 sets out principles of governance – including inclusiveness – for standards-development in support of EU legislation and policies, describes the procedures and regulates the financing methods and recourse mechanisms.

The purpose of this evaluation is to present an informed analysis of the Regulation's current performance, assessing its effectiveness, efficiency, coherence, EU added value and relevance, in light of the significantly changed political and economic landscape. The ongoing green and digital transformation of the EU economy, together with current geo-economic challenges, are putting European standardisation to the test. The [EU standardisation strategy](#) of February 2022 outlined the new political, economic and global context and announced that Regulation (EU) 1025/2012 would be evaluated. The case law of the Court of Justice of the European Union (CJEU) during the last decade has also had a significant impact on the Regulation's implementation.

The evaluation was supported by a study, which was carried out at the Commission's request by a consortium composed of Intellera Consulting, Fraunhofer ISI and Trinomics B.V. It has been further informed by dedicated workshops and direct interactions with stakeholders, including academic experts.

The evaluation shows that the Regulation has led to some improvements in the speed and inclusiveness of standards-development, yet it struggles to meet current market, policy and legal needs. The results are summarised below.

1. Effectiveness

The Regulation has been moderately effective in reducing the time it takes to develop harmonised standards for the European Commission in support of EU policies and legislation. However, with a total average duration of six years (three of which for the drafting and consensus-building stage), the standardisation process is still considered to be much too slow, in particular in relation to legislative requirements, market needs and global competition. Delays, complexities and inefficiencies in the standardisation process hamper the positive impacts of harmonised standards on the competitiveness of EU companies. Among the root causes are i) procedural hurdles; ii) recurrent quality issues in draft standards combined with the new safeguards and control mechanisms put in place as a result of case law; iii) the increasing pressure of legislation and market needs on the ability of the European standardisation organisations (ESOs) to deliver on time; iv) communication and coordination problems; and (v) insufficient deployment of digital technologies. While the ESOs and national standardisation bodies (NSBs), regardless of their business model, are all considered

to have a strong incentive to work on the development of harmonised standards (given the intrinsic relevance and legal value of harmonised standards), they rely heavily on stakeholder involvement and may lack an incentive to adapt or accelerate their ways of working, as the Regulation only allows standardisation requests to be addressed to the three ESOs. Moreover, there is a lack of alternatives for resolving situations when harmonised standards are not delivered in a timely manner. As regards stakeholder participation, the Regulation has been moderately effective in increasing the participation of SMEs and civil society stakeholders in standards development. However, their real impact is often considered limited and they often lack the resources, capacity and skills to participate effectively in complex and time-consuming standardisation processes, not only at European but also at national and international level. The Regulation's effectiveness on the increased use of ICT specifications has been limited, although this has been compensated by the fact that new digital legislation has been adopted that relies on the use of harmonised standards.

2. Efficiency

The evaluation of efficiency faced significant data collection challenges, in particular concerning the cost-benefit analysis. This analysis relies on information on industry costs collected through public consultations, targeted surveys and interviews, and subsequent triangulation of the evidence. The Regulation has generated some direct reporting obligations for the ESOs, NSBs, the 'Annex III organisations' (SMEs and civil society organisations) and the European Commission, which have been deemed proportionate, partly due to simplification efforts already made. Administrative costs for financing (preparation of proposals and activity reports) increased but were in line with the Financial Regulations. As regards indirect compliance costs for stakeholders (business and civil society organisations), while there is a lack of solid data, the evaluation's cost-benefit analysis suggests that the benefits of the Regulation outweigh the costs incurred. Nevertheless, the costs of expert participation in standard-setting processes are significant. The ESOs have increasingly deployed digital tools to facilitate the standards-development process, but progress lags behind other standards-development organisations. The system of formal objections to harmonised standards is considered to be too long, cumbersome and inefficient. While the initial objective of the Commission proposal was to simplify procedures, over the last ten years, new administrative and adoption procedures have been put in place in line with CJEU case law, which has clarified the legal standing of harmonised standards as part of EU law and the central role of the Commission in the whole harmonised standards-development process. While these procedural steps are necessary, they have made the overall process more burdensome and less efficient. Simplification opportunities include further improved reporting and monitoring procedures, procedural improvements and accelerated standard-development processes, yet the rigidity in the standardisation process outlined by the Regulation and its full reliance on the standardisation capabilities of the three ESOs limit opportunities for simplification and acceleration.

3. Coherence

The evaluation found that the Regulation was internally coherent. Externally, the Regulation contributed to more coherence on the use of harmonised standards across the EU legislative *acquis*, especially in legal instruments falling under the new legislative framework. Some exceptions persist, such as the terminology used in the [General Product Safety Regulation](#). The evaluation also found that in some policy areas, the legislators decided, for justified reasons, to draw on a different system of standards-development, as with the [Corporate Sustainability Reporting Directive](#), which set up a separate standards-development body, or the Regulation on the European Health Data Space whereby the Commission adopts common specifications via implementing acts as a primary means to implement the essential requirements.

4. EU value added

The Regulation has provided EU added value and European standardisation is appreciated by stakeholders. One of the objectives of the Regulation was to remove existing and conflicting national standards, and the Regulation has achieved this. If the Regulation were to be withdrawn and replaced by national laws, this would create a significant burden on trading within the Single Market, which would not be beneficial.

5. Relevance

While the Regulation's initial objectives remain relevant, they do not fully align with current strategic priorities outlined in the 2022 standardisation strategy. Weaknesses in the current framework have been made more evident by external factors, such as (i) accelerated technology cycles in the digital and green fields; (ii) an ageing population of technical experts; (iii) geo-economic developments; (iv) the increased assertiveness of non-EU countries in international standardisation; and (v) CJEU case law. In particular, the framework struggles to deliver in emerging technology areas, including those that are key to the EU's policy priorities and the competitiveness of its businesses. The EU's role as a global standard-setter is increasingly challenged, requiring the EU to coordinate better and to position itself faster in international standardisation. With most harmonised standards currently cited in the Official Journal of the European Union being more than five years old, more responsiveness to innovation and a better anticipation of future standardisation needs (also at the pre-normative stage) are warranted. Furthermore, the implementation of CJEU case law has resulted in procedural complexities and has highlighted the need for more transparency and accessibility to harmonised standards. Alternative routes to standardisation are increasingly considered and may be needed more broadly to meet future needs.