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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{SEC(2026) 780 final} - {SWD(2026) 785 final} - {SWD(2026) 786 final} - {SWD(2026) 787 final}

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Standardisation is a pillar of the internal market, enabling the free movement of goods and services while fostering interoperability, quality, and consumer trust. By providing a presumption of conformity with Union legislation, harmonised standards simplify compliance for businesses, reduce costs, and prevent market fragmentation. Beyond its role in the internal market, standardisation has increasingly become a strategic industrial policy tool, driving innovation, supporting the adoption of new technologies, and reinforcing the Union's competitiveness and strategic autonomy.

The European Council Conclusions of March 2026[1] underscored the need to 'boost the Union's competitiveness, increase its resilience and enhance its strategic autonomy and economic security', placing the deepening and integration of the internal market at the heart of the 'One Europe, One Market' roadmap. The Council explicitly called for 'enhancing enforcement of EU standards' as a priority, building on the Commission's Competitiveness Compass[2] and the Single Market Strategy[3], which identified delays in standardisation as one of the 'terrible 10' barriers to a fully functional internal market. In response, the Commission committed to revise Regulation (EU) No 1025/2012 of the European Parliament and of the Council[4].

This proposal aims to modernise the European standardisation system by addressing four key challenges. Excessive delays in the development of harmonised standards hinder the timely implementation of Union legislation and weaken the Union's ability to take the lead in emerging technologies (*e.g.*, AI, cybersecurity, green tech). Insufficient and unbalanced stakeholder participation, particularly among small and medium-sized enterprises ('SMEs'), startups and scaleups, civil society, and research and innovation stakeholders, risk leading to lower-quality standards that do not reflect adequately diverse societal and economic needs. Uncertainty surrounding the financial sustainability of the European standardisation system, following case law of the Court of Justice of the European Union ('CJEU')[5] requiring free access to harmonised standards, challenges the revenue model of some European standardisation organisations. The Union influence in global standardisation is declining, particularly in strategic technologies.

• Consistency with existing policy provisions in the policy area

Regulation (EU) No 1025/2012 establishes the legal framework for the European standardisation system, governing the collaboration between the Commission, the European standardisation organisations, namely the European Committee for Standardization ('CEN'), the Committee for Electrotechnical Standardization ('CENELEC') and the European

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1 EUCO 1/26, European Council meeting (19 March 2026) – Conclusions.

2 COM(2025) 30 final, 29.1.2025.

3 COM(2025) 500 final, 21.5.2025.

4 Regulation (EU) 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 1673/2006/EC of the European Parliament and of the Council Text (OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj).

5 Judgment of 27 October 2016, James Elliott Construction Ltd v Irish Asphalt Ltd., C-613/14, EU:C:2016:821; Judgment of 5 March 2024, Public.Resource.Org and Right to Know v Commission, C-588/21 P, EU:C:2024:201.

Telecommunication Standards Institute ('ETSI'), and national standardisation bodies in developing standards and standardisation deliverables to support Union legislation and policies. That Regulation's primary focus is delivering harmonised standards adopted following a Commission request to one or several European standardisation organisations to support Union harmonisation legislation. Harmonised standards allow businesses to demonstrate conformity with the requirements set out in Union harmonisation legislation which those harmonised standards or parts thereof aim to cover, facilitating market access and reducing compliance costs.

Regulation (EU) No 1025/2012 operates in synergy with the New Legislative Framework[6], which establishes a common legal framework for 31 sectoral product acts, ensuring that products compliant with harmonised standards can circulate freely in the internal market. Over time, the scope of standardisation in support of Union legislation and policies has expanded beyond product harmonisation to support digital policies (*e.g.*, cybersecurity, AI), green transition initiatives (*e.g.*, the Green Deal[7] and the Clean Industrial Deal[8]), and sectoral industrial strategies (*e.g.*, housing[9], bioeconomy[10]).

Key amendments to the Union regulatory framework on standardisation include:

- the 2022 revision of Regulation (EU) No 1025/2012[11], which restricted decision-making on standardisation requests to EU/EEA national standardisation bodies only, reinforcing the EU's autonomy in standard-setting;
- the 2025 Omnibus IV proposal on digitalisation and common specifications[12], which proposed the introduction of common specifications as a fallback when harmonised standards are unavailable, enhancing legal certainty for businesses.

The CJEU has, in particular, clarified that harmonised standards form part of EU law and must be freely accessible under the principles of transparency and the rule of law. This aligns with the Union's democratic values, but poses financial challenges for European standardisation organisations, particularly CEN and CENELEC, whose revenues rely partly on the sales of harmonised standards. ETSI, which provides free access to its standards, including its harmonised standards, is not affected to the same degree.

This proposal builds on the existing framework while addressing structural weaknesses to ensure the European standardisation system remains fit for purpose in a rapidly evolving technological and geopolitical landscape.

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6 Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93 (OJ L 218, 13.8.2008, pp. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj) and Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, pp. 82, ELI: http://data.europa.eu/eli/dec/2008/768(1)/oj).

7 COM(2019) 640 final, 11.12.2019.

8 COM(2025) 85 final, 26.2.2025.

9 COM(2025) 991 final, 16.12.2025.

10 COM(2025) 960 final, 27.11.2025.

11 Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) 1025/2012 as regards decisions of European standardisation organisations concerning European standards and European standardisation deliverables (OJ L 323, 19.12.2022, pp. 1, ELI: http://data.europa.eu/eli/reg/2022/2480/oj).

12 COM(2025) 503 final and COM(2025) 504 final, 21.5.2025.

- **Consistency with other Union policies**

Standardisation is a horizontal policy tool that contributes to the functioning of the internal market, ensures interoperability and consumer protection, and promotes competitiveness. It plays a critical role in implementing the Single Market Strategy and the 'One Europe, One Market roadmap', and aims to reduce market fragmentation and enhance the enforcement of Union product rules.

Standards are essential in the digital sector: they ensure the interoperability of digital technologies and are the foundations of an effective digital single market. They also facilitate economies of scale, foster research and innovation and promote competition by keeping markets open. Standards underpin Union legislation in the digital sector, such as Regulation (EU) 2024/1689 of the European Parliament and of the Council[13] and Regulation (EU) 2024/2847 of the European Parliament and of the Council[14], to ensure that new technologies are safe, interoperable and align with Union values. This proposal will help in accelerating the development of standards in these areas, supporting the Digital Decade targets[15]and reinforcing the Union's digital sovereignty.

Standardisation is also essential for the green transition, enabling the implementation of the European Green Deal and the Clean Industrial Deal by providing technical solutions for decarbonisation, circular economy, and sustainable resource management.

As regards the international level, the proposal builds upon the 2022 Standardisation Strategy[16], which seeks to strengthen the Union's influence in global standard-setting bodies and ensure that international standards reflect Union priorities and values. This is particularly important in strategic technologies, where third countries such as the US and China are actively shaping global standards to promote their industrial and geopolitical interests.

Finally, the proposal supports social inclusion by promoting broader stakeholder participation in standardisation, ensuring that standards reflect the needs of SMEs, including startups and scaleups, civil society and consumers, and benefit from the participation of the research and innovation stakeholders.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legal basis for this Regulation is Article 114 of the Treaty on the Functioning of the European Union for the adoption of measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

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13 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) 300/2008, (EU) 167/2013, (EU) 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

14 Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

15 COM(2021) 118 final, 9.3.2021.

16 COM(2022) 31 final, 2.2.2022.

- **Subsidiarity (for non-exclusive competence)**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Union. The objectives of the proposal cannot be sufficiently achieved by Member States for the following reasons:

- European standardisation supports Union legislation and policies by facilitating the functioning of the internal market. Harmonised standards replace conflicting national standards, which may create technical barriers to trade. The problems affecting the European standardisation system, such as delays in standards development and concerns regarding financial sustainability, are shared across all Member States and require a solution at Union level.
- Member States acting individually cannot effectively address these challenges. Without Union action, the identified problems would persist, leading to fragmentation, increased compliance costs, and reduced competitiveness. National measures would be insufficient to ensure a coherent and efficient standardisation system that fosters the same standards across the Union.

Union action will better achieve the objectives of the proposal for the following reasons:

- The proposal will improve the functioning of internal market by ensuring timely and high-quality standards and standardisation deliverables in support of Union legislation and policies.
- The proposal will reduce compliance costs for businesses, increase trade, and strengthen the Union's influence in international standardisation.
- The proposal will support key Union policies that rely on standards and standardisation deliverables for their implementation.

Therefore, the proposal complies with the subsidiarity principle.

- **Proportionality**

The proposed revision respects the principle of proportionality, as set out in Article 5 of the Treaty on European Union, and follows what is appropriate and necessary to achieve the objectives of ensuring a more responsive, sustainable and internationally influent European standardisation system. The proposal introduces targeted improvements to the functioning of the European standardisation system to achieve the initiative's objectives without imposing unnecessary burdens on stakeholders, as outlined in the Impact Assessment of the initiative.

The measures introduced to make the European standardisation system more responsive rely on the current framework for European standardisation and aim to improve the performance of the European standardisation organisations, while introducing the possibility to rely on designated standards development organisations in targeted situations, where the European standardisation organisations would not be able to deliver high-quality standards in a timely manner.

The proposal also increases the requirements for European standardisation organisations, national standardisation bodies and designated standards development organisations to make the European standardisation process more inclusive. The increased requirements are targeted at the national level where the barriers to participate in standardisation are the highest. The obligation to provide free and unrestricted access to referenced standards is necessary to achieve the objective of the initiative. Its implementation takes into account the need to ensure the financial viability of the European standardisation system.

The improved coordination of European stakeholders in international standardisation is necessary to consolidate the Union influence in international standardisation and is achieved through targeted coordination mechanisms, with the participation of both the Commission and Member States. The possibility to restrict participation to actors from the Union or to diverge from international standards in the European standardisation process in support of Union legislation and policies is necessary to promote the Union's economic security and strategic autonomy, and codifies existing practices, without undermining the 'international first' principle, whereby European standards should first seek to align with international standards.

- **Choice of the instrument**

A Regulation is the appropriate instrument for the initiative, which revises an existing Regulation. The legal instrument must be of general application, as it concerns standards and standardisation deliverables that aim at having a direct effect throughout the Union. In addition, the legislative instrument contains obligations that are directly applicable to the European standardisation organisations, the national standardisation bodies, designated standards development organisations, European stakeholder organisations and the Commission.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The evaluation of Regulation (EU) No 1025/2012[17] aimed to assess its performance and impact between 2013 and 2023, in particular by assessing whether standards the Commission requested under that Regulation have been delivered in an effective, inclusive and timely manner. The evaluation provided an evidence-based assessment of the effectiveness, efficiency, relevance, coherence and EU added value of the Regulation, and its findings informed both the drafting process and the accompanying Impact Assessment.

In relation to the original objectives of Regulation (EU) No 1025/2012, the evaluation found that (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 withdrawn in favour of European standards, and (iii) the European standardisation system became more inclusive of societal stakeholders and SMEs.

However, the evaluation also identified key shortcomings that directly underpin the problems addressed in this proposal. The evaluation found that the development of harmonised standards is still too slow, on average six years, and often misses legislative deadlines. This supports the proposal's focus on increasing the speed of standardisation in support of Union legislation and policies to limit delays in the availability of standards, which increase compliance costs and legal uncertainty for businesses.

The evaluation also pointed out the rigidity in the standard-development process set up by Regulation (EU) No 1025/2012. Its reliance on the standardisation capabilities of the three European standardisation organisations limits opportunities for simplification and acceleration. The evaluation also revealed insufficient SME and stakeholder participation, particularly in emerging technologies. The evaluation highlighted the financial challenges for European standardisation organisations linked to providing free access to harmonised standards in line with the recent case-law of the CJEU. Additionally, it noted growing fragmentation linked to alternative standardisation routes such as common specifications,

[17] Evaluation of Regulation (EU) 1025/2012 on European standardisation, SWD(2025) 170 final, 23.6.2025.

supporting the proposal's objective of creating a coherent framework for standards and common specifications. Finally, the evaluation highlighted the Union's declining influence in international standardisation, which the proposal aims to address.

These findings demonstrate that the current framework falls short in speed, inclusiveness, and global relevance, thus justifying the proposed reform of Regulation (EU) No 1025/2012.

- **Stakeholder consultations**

In line with the Better Regulation Guidelines, the Commission conducted an ambitious and inclusive consultation process designed to gather reliable evidence from the full range of standardisation stakeholders. A call for evidence ran between 23 June 2025 and 21 July 2025 generating a total of 198 valid contributions from business associations, non-governmental organisations, businesses, public authorities and other stakeholders, overwhelmingly from EU and EEA countries. The open public consultation on the initiative took place from 24 September to 17 December 2025. 599 valid replies were submitted from 32 different countries, stemming in majority from business associations, businesses, including SMEs, non-governmental organisations and citizens.

The call for evidence and the open public consultation were complemented by a targeted survey for industry organisations and companies, including SMEs, to gather specific feedback on costs and benefits to be expected from the different options, in-depth interviews with European standardisation organisations, national standardisation bodies, and European stakeholder organisations and five workshops with SMEs, national standardisation bodies and the members of the High-Level Forum on European standardisation.

The results revealed preferences and concerns regarding the policy options for the proposal. Industry and SMEs favoured measures to increase responsiveness, such as using technical specifications for temporary presumption of conformity and digitalising standardisation processes. They saw potential benefits in introducing greater flexibility for obtaining standards and standardisation deliverables in support of Union legislation and policies, for instance through the involvement of other standards development organisations than the European standardisation organisations but expressed concerns about possible fragmentation and inclusiveness. European standardisation organisations and European stakeholder organisations supported measures that would preserve the current structure of the European standardisation system, based on the exclusive right of European standardisation organisations to deliver standards in support of Union legislation and policies, while supporting targeted improvements and simplification.

European standardisation organisations and national standardisation bodies opposed the implementation of the case-law of the CJEU on access to standards through the publication of standards in the *Official Journal of the European Union* as it would threaten their revenue models. Other stakeholders expressed support for free and unrestricted access to standards in support of Union legislation and policies.

Industry, SMEs, European standardisation organisations and national standardisation bodies highlighted the importance of alignment between European and international standardisation and called for targeted possibilities for European standardisation to diverge from international standardisation due to risks of duplication and diminished Union's influence. All stakeholder groups rejected an overhaul of the current European standardisation system, whereby standards in support of Union legislation and policies could be requested to any standards development organisations, citing risks of system fragmentation, reduced inclusiveness, and financial instability for national standardisation bodies and European standardisation organisations.

The Commission considered these views carefully. Stakeholders agreed on the need for faster, more inclusive, and globally competitive European standardisation and supported measures that would improve the functioning of the European standardisation system in a targeted and incremental manner, with European standardisation organisations at the centre. The Commission implemented these views in the proposal but introduced additional flexibilities in the standardisation process in support of Union legislation and policies, notably through the possibility to request standards to other standards development organisations than the three European standardisation organisations. It also proposes clear requirements on access to standards in support of Union legislation and policies. The Commission considers these measures necessary to address the systemic challenges identified in the evaluation, particularly regarding the Union's global competitiveness, the legal certainty vis-à-vis potential future judgments from the CJEU, the need for greater flexibility in emerging technological fields and for a European standardisation system that is future-proof.

- **Collection and use of expertise**

The Commission has consulted stakeholders through a call for evidence, open public consultations, targeted surveys, in-depth interviews, bilateral meetings and workshops. It has relied on an evaluation study on the current Regulation (EU) No 1025/2012[18] and on a study supporting the impact assessment, both conducted by an external contractor[19]. The Commission also regularly consulted the High-Level Forum on European standardisation.

- **Impact assessment**

The proposal was supported by an Impact Assessment which received a positive opinion from the Regulatory Scrutiny Board. Following the positive opinion from the Regulatory Scrutiny Board, the Impact Assessment was amended to incorporate the Board's comments, in particular to improve the analysis on the link between participation of stakeholders and quality of the harmonised standards, to clarify the definition of the second specific objective of the initiative and to improve the description of policy options and the efficiency analysis.

The impact assessment examined three policy options which differ mainly in the degree of changes introduced to the current European standardisation system and in the balance they each strike between responsiveness, financial viability, inclusiveness and strategic autonomy.

Option 1 would preserve the current architecture of the European standardisation system, with the European standardisation organisations remaining the only organisations that may receive standardisation requests from the Commission, while modernising the system through targeted improvements. These improvements would include making better use of technical specifications developed outside the European standardisation organisations by other standards development organisations, introducing the possibility to grant presumption of conformity to standardisation deliverables until a harmonised standard becomes available and creating a horizontal framework for the Commission's use of common specifications. The option also improves the strategic planning of standardisation needs, simplifies and clarifies procedures for requesting, implementing and assessing standards in support of Union legislation and policies, and introduces deadlines at each step of the process. It also introduces measures to strengthen participation, transparency and Union coordination in international standardisation. This option is the least disruptive and preserves the current institutional and

[18] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fraunhofer ISI, Intellera Consulting and Trinomics B.V, Evaluation study of Regulation (EU) 1025/2012 on European standardisation – Final report.

[19] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Intellera Consulting and Fraunhofer ISI, Impact Assessment supporting study accompanying the Revision of the EU Standardisation Regulation No. 1025/2012 – Final report.

financial model, notably by maintaining the *status quo* on access to standards in support of Union legislation and policies. It would improve responsiveness, notably by reducing the average time needed to obtain a harmonised standard by around one year compared to the baseline. However, it offers limited additional flexibility where European standardisation organisations are unable to deliver standards in a timely manner and therefore risks of falling short of addressing urgent competitiveness or technological sovereignty needs.

Option 2 builds on Option 1 and retains the European standardisation organisations as the cornerstone of the European standardisation system but adds two important measures to increase its flexibility and responsiveness. First, the Commission could address standardisation requests to designated alternative standards development organisations if European standardisation organisations do not deliver or do not meet quality or timing expectations, or if a standards development organisation is objectively better placed to develop the requested standards. Second, free and unrestricted access to referenced standards would be provided through repositories managed by the European standardisation organisations and designated standards development organisations where relevant. This option also strengthens inclusiveness at national level, creates a Centre of Excellence on European Standardisation and introduces targeted derogations from the 'international first' principle in strategic or sovereignty-sensitive cases.

Option 2 would improve responsiveness more effectively than Option 1, because it introduces a credible fall-back solution when the existing system is unable to deliver requested standards, while also creating stronger incentives for timely delivery by the European standardisation organisations. Its effect on average delivery times is expected to remain limited overall, since recourse to alternative standards development organisations would be used only in a small number of cases, but in those cases the benefits could be significant. Option 2 also ensures the financial viability of the system, although requiring adaptation of the business models of some European standardisation organisations, while improving legal certainty and inclusiveness. It would give the Union more international influence than Option 1 because it combines stronger Union coordination with greater strategic flexibility to protect the interests of the Union where necessary.

Option 3 would constitute a fundamental redesign of the European standardisation system. It would end the European standardisation organisations' exclusive role, allowing the Commission to choose any suitable standards development organisations for each request. It would establish an EU Standardisation Office to manage the European standardisation system centrally and make standards in support of Union legislation and policies publicly available in the *Official Journal of the European Union*.

This option is potentially highly effective in terms of responsiveness, as it would allow selecting the most appropriate organisation in each case. However, that benefit is uncertain in practice, since the capacity of alternative standards development organisations to deliver harmonised standards consistently in line with Union expectations has not yet been tested. More importantly, this option challenges the financial viability of the European standardisation system by removing core incentives for European standardisation organisations and alternate standards development organisations to develop standards in support of Union legislation and policies. This risks weakening stakeholder participation, particularly from industry, and could undermine the stability of the system. Its effect on international influence is overall neutral: while it increases strategic control, it could also reduce alignment with international standards and thereby diminish the Union's influence in international standardisation bodies.

On balance, Option 2 was considered to be the best policy choice. It offers the most proportionate response to the problems identified. It preserves the key strengths of the current European standardisation system, including the central role of the European standardisation organisations, while introducing targeted flexibilities to address cases where the system is currently too slow or insufficiently adaptive. It also improves public access to standards and strengthens inclusiveness, without creating the disruption and risks associated by fully centralising standardisation under Option 3. Compared with Option 1, it better equips the Union to respond to urgent technological, competitiveness and strategic challenges. Compared with Option 3, it achieves these benefits in a more predictable, legally robust and financially sustainable manner.

Option 2 is expected to generate overall positive economic effects by improving the responsiveness of the European standardisation system, while also creating some adjustment costs and implementation risks for public and private actors. The main direct economic benefit of Option 2 stems from the faster and more predictable development of harmonised standards. The option is expected to generate annual administrative costs savings for businesses estimated at EUR 295 million per year, linked to savings in compliance costs stemming from the earlier availability of harmonised standards. These gains are particularly relevant in fast-moving sectors, such as digital technologies and clean tech, where delays in standards can slow down innovation, product deployment and regulatory compliance. Free access to harmonised standards also creates sizeable direct benefits for users of standards. Those indirect cost savings are estimated at approximately EUR 30 million per year for businesses from removing paywalls for harmonised standards. These savings are expected to overwhelmingly benefit SMEs, as smaller firms are more sensitive to access costs and information barriers.

These benefits, however, entail administrative and compliance costs for European standardisation organisations and national standardisation bodies. Ensuring free and unrestricted access to harmonised standards could reduce the revenues of national standardisation bodies by up to EUR 30 million annually, corresponding to around 15 % of their total annual standards sales in the EU and 6 % of their total annual revenues. Additional costs would also arise from inclusiveness requirements: the related obligations for national standardisation bodies are estimated at around EUR 1,9 million per year. The use of alternative standards development organisations to deliver standards in support of Union legislation and policies could generate duplication costs for businesses to engage in potential parallel standardisation processes or monitor multiple standard-setting channels, estimated at EUR 4,5 million per year. The implementation of Option 2 would also require 7,5 additional full-time equivalents (FTEs) in the Centre of Excellence on European Standardisation and in the services of the Commission relying on this Regulation to support their legislation and policies, through internal redeployment (5,5 FTEs) and additional external staff (2 FTEs).

The Impact Assessment has not considered the environmental and social impacts of Option 2. As a horizontal initiative supporting sectoral products and services legislation, the direct environmental and social impacts are negligible. Standards in support of Union legislation and policies, however, can make an important contribution to the Union environmental, social or societal objectives, such as for instance improving accessibility, safety and inclusivity products and services in the internal market. However, such effects directly depend on the sectoral legislation and on the definition of essential requirements. A more effective standardisation system would help sectoral legislation achieve environmental and social objectives.

- **Regulatory fitness and simplification**

This initiative responds to urgent political and economic priorities set by the European Council, the Commission's Single Market Strategy and its Standardisation Strategy. It seeks to strengthen the European standardisation system's efficiency, inclusivity, and global influence while ensuring its long-term financial viability.

The proposal will bring simplification and improved efficiency primarily through the increased availability of harmonised standards, which are themselves simplification tools for businesses to access the internal market. Making harmonised standards available faster will significantly reduce businesses' compliance costs and facilitate the conformity assessment of their products and services. The new obligations for European standardisation organisations and national standardisation bodies relating to inclusiveness of civil society organisations, research and innovation stakeholders and SMEs will facilitate their participation in the standardisation process, notably by reducing their participation costs. The repositories for standards and standardisation deliverables in support of Union legislation and policies will simplify access to standards for all stakeholders, not only reducing costs for users through free access but also facilitating consultation and use.

The simplification is expected to be particularly relevant for SMEs. The Impact Assessment estimates that 78 % of savings related to conformity assessment would accrue to SMEs, suggesting that improved access and usability of standards in support of Union legislation and policies could have a strong pro-SME effect. The proposal also includes measures that specifically support SMEs' participation in standardisation.

The proposal is expected to strengthen the Union sectoral competitiveness. Faster standard development can give EU businesses a first-mover advantage, helping them innovate more quickly and bring products to market sooner. Free access to harmonised standards supports faster diffusion of innovation, as firms can integrate the latest standards into products without additional purchase costs. Greater involvement of the research community and of public authorities will improve the relevance of standards, support the uptake of new technologies, including by SMEs, startups and scaleups and facilitate the identification, validation and transfer of relevant research and innovation results into standardisation activities. The proposal is also expected to have positive impact on trade, as the Impact Assessment identifies a link between an increase in the stock of harmonised standards and intra- and extra-EU trade. The alignment between European and international standards helps reduce technical barriers to trade and improves the ability of European businesses to access international markets.

The proposal fosters the digitalisation of the European standardisation system for the development of standards, their evolution into 'smart standards', where the content of the standards is complemented by additional data and information to facilitate their use and their integration in the business processes of market operators, and the cooperation between the Commission and European standardisation organisations. The creation of the EU Standards Platform will make available up-to-date information on the development status of requested standards and standardisation deliverables, provide detailed information on the performance of the European standardisation system and on the implementation of this Regulation and will foster a digital approach to standardisation in support of Union legislation and policies.

- **Fundamental rights**

The proposal does not impact the Charter of Fundamental Rights.

4. BUDGETARY IMPLICATIONS

Without prejudice to the outcome of the negotiations on the 2028-2034 Multiannual Financial Framework, the proposal is estimated to require the use of operational appropriations that are commensurate with the current budget allocated to standardisation activities within the Single Market Programme[20]. All activities, in particular all new activities created by the proposal, could be financed under the corresponding budget within the Single Market and Customs Programme[2121], including through redeployment where necessary. The indicative estimate is EUR 183 million over the programming period 2028-2034, at current price, based on annual expenditures for standardisation within the Single Market Programme of EUR 23,7 million in 2027. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the 2028-2034 Multiannual Financial Framework and thereafter shall be determined through the annual budgetary procedure.

The proposal may trigger the need to redeploy the standardisation appropriations within the Single Market and Customs Programme. Free and unrestricted access to standards in support of Union legislation and policies may challenge the financial sustainability of some national standardisation bodies, which rely to various degrees on their sales, and in turn, the current functioning of CEN and CENELEC. Free and unrestricted access to such standards implies a shift of the financial burden of the standardisation development process from users, through their purchase of standards, to the European standardisation organisations and national standardisation bodies, through a loss of revenues. This additional financial burden on European standardisation organisations and national standardisation bodies could decrease their ability to develop standards and standardisation deliverables in support of Union legislation and policies and to accept standardisation requests from the Commission.

The financial impact on national standardisation bodies could be mitigated by their developing new services to users, based on the copyrights they claim on the standards they develop, such as smart standards. However, targeted support from the Union budget may be necessary to ensure the financial sustainability of national standardisation bodies, in particular the national standardisation bodies most financially exposed to the free access to standards. The Commission may, subject to the relevant provisions of the Single Market and Customs Programme and programming decisions, grant that support through an increase in operating grants to European standardisation organisations which would then distribute it to relevant national standardisation bodies. This increase in operating grants would be financed through redeployment within the Single Market and Customs Programme.

The proposal provides for the creation of a Centre of Excellence on European Standardisation, to support its implementation. It also provides for strengthening the network of experts from the Commission, relevant EU agencies and Member States involved in requesting, developing and assessing standards in support of Union legislation and policies. The Centre of Excellence would host the new tasks of the Commission stemming from the proposal, in particular concerning requests to designated standards development organisations and the improvement of the coordination of EU actors in international standardisation. It would also improve the

[20] Regulation (EU) 2021/690 of the European parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014 (OJ L 153, 3.5.2021, pp. 1–47).

[21] COM(2025) 590 final, 16.07.2025.

coordination of the internal network of standardisation experts across Commission services. The Centre of Excellence would gather a total of 20 FTEs with a central support and coordination role. The additional resources needed to implement the proposal would be covered through internal redeployments within the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (1,5 FTEs), internal redeployments within the Commission's services relying on the Standardisation Regulation to support their legislation and policies (4 FTEs) and through 2 additional external FTEs, which could be financed under the administrative line of the Single Market and Customs Programme.

Estimated impacts and staffing for 2028 and beyond are indicative and without prejudice to the outcome of the negotiations on the 2028-2034 Multiannual Financial Framework. Further detail is set out in the Legislative Financial and Digital Statement accompanying this proposal.

5. OTHER ELEMENTS

• Implementation plans and monitoring, evaluation and reporting arrangements

The improved monitoring of the implementation of this Regulation by the Commission is a key dimension of the proposal. The Commission will monitor the improvements in the performance and responsiveness of the European standardisation system by setting up key performance indicators on speed, timeliness, quality and flexibility, which it will regularly monitor, with the contribution of European standardisation organisations and designated standards development organisations.

The overall influence of the Union in international standardisation will be monitored through the Union's involvement in international standardisation organisations and the ability of the Union to ensure strategic autonomy and actual influence in international standardisation organisations. Monitoring will rely on data reported by the European standardisation organisations and the designated standards development organisation through the EU Standards Platform, as well as on annual reports submitted by European standardisation organisations and European stakeholder organisations.

In addition, the proposal requires the Commission to submit a report to the European Parliament and the Council on the implementation of this Regulation five years after its entry into force, and every five years thereafter, as well as an evaluation of the proposal after five years of its application.

• Detailed explanation of the specific provisions of the proposal

Chapter I outlines the general provisions of the Regulation, namely its subject matter and definitions. It states that the Regulation lays down rules regarding (i) requesting, developing and referencing standards and standardisation deliverables in support of Union legislation and policies, (ii) the functioning of the European standardisation system through the cooperation between the actors involved, (iii) the participation of European stakeholders in standardisation and (iv) the possibility to adopt common specifications as a fall-back option to harmonised standards if the European standardisation system is not able to deliver quality standards or standardisation deliverables in a timely manner. It also revises the definitions needed for the purposes of this Regulation and, in particular, specifies that the term 'harmonised standard' should be used for standards developed following a standardisation request from the Commission, the reference of which has been published in the *Official Journal of the European Union* and which provides a presumption of conformity with the requirements, set

out in the relevant Union legislation, which it aims to cover. It introduces the broader concept of referenced standards and standardisation deliverables, which includes all standards and standardisation deliverables requested by the Commission, the references of which have been published in the *Official Journal of the European Union*.

Chapter II sets out the principles for European standardisation that apply for the development of all standards and standardisation deliverables requested by the Commission in support of Union legislation and policies, either from European standardisation organisations or from designated standards development organisations. It sets out that the development of such standards and standardisation deliverables must be transparent and that referenced standards and standardisation deliverables must be freely accessible. It also deals with digitalising the European standardisation system, sets out objectives for the financing of the European standardisation system by the Union, in particular to foster its financial sustainability, and revises the strategic planning of standardisation needs to support Union legislation and policies through the annual Union work programme on European standardisation.

Chapter III covers standards and standardisation deliverables requested from the European standardisation organisations.

Section I sets outs the specific role European standardisation organisations and national standardisation bodies play in the European standardisation system. It establishes the principle of European decision-making in these organisations for standards and standardisation deliverables requested by the Commission and introduces the possibility to amend the list of European standardisation organisations through a delegated act. It also lays down the cooperation between the Commission and European standardisation organisations based on key performance indicators to be regularly assessed by the Commission. Finally, it reinforces the rules on the transparency of the work programmes and standards and standardisation deliverables adopted by European standardisation organisations and national standardisation bodies.

Section II addresses the inclusiveness of the standardisation process by European standardisation organisation and national standardisation bodies. It requires them to enable appropriate representation of relevant stakeholders, namely SMEs, consumer organisations, environmental and social stakeholders, research and innovation stakeholders as well as public authorities. It introduces the European stakeholder organisations, which are selected by the Commission based on an open and non-discriminatory process, to represent the SMEs, social, environmental and consumer interests in the European standardisation process.

Section III establishes the obligation for the Commission to consult European standardisation organisations before adopting a standardisation request. It also specifies the conditions that the Commission may include in the standardisation request and establishes the procedural steps with deadlines for adopting standardisation requests. This section also sets out the requirements for implementing the standardisation requests by European standardisation organisations and defines the assessment procedure, whereby the Commission assesses whether the reference of a standard or standardisation deliverable of the European standardisation organisations developed in response to a standardisation request should be published in the *Official Journal of the European Union*.

Chapter IV sets out the framework for requesting standards and standardisation deliverables from designated standards development organisations. It sets out the procedure and requirements for designating standards development organisations to which the Commission may address a standardisation request. Furthermore, it sets out the procedure for requesting and assessing standards and standardisation deliverables from designated standards development organisations and their implementation of the request, similar to the procedure

for European standardisation organisations. It specifies that the Commission assesses the coherence of standards and standardisation deliverables from designated standards development organisations with the existing referenced standards and standardisation deliverables. It sets out the grounds and process for the Commission to adopt common specifications. It establishes a safeguard notification mechanism to alert, and, where necessary, withdraw common specification or the reference to a referenced standard or standardisation deliverable, which does not satisfy the requirements it aims to cover.

Chapter V outlines the importance of international standardisation and promotes European coordination to increase the Union's influence in international standardisation bodies. It lays out the international first principle, whereas European standardisation organisations should coordinate with international standardisation bodies, as well as possible exceptions to the principle to support the Union's strategic autonomy. It also requires that European standardisation organisations and designated standards development organisations inform the Commission of cooperation agreements with other standards development organisations which may affect their standardisation activities as regards the development of requested standards and standardisation deliverables.

Chapter VI establishes the Centre of Excellence on European Standardisation and sets out the rules for the implementation of this Regulation, including evaluation, monitoring, review, exercising the delegation power and the role of the committee.

Chapter VII establishes the common, final provisions of the Regulation by setting out the rules for entry into force and application and repeals Regulation (EU) No 1025/2012 and Article 48 of Regulation (EU) 2023/988 of the European Parliament and of the Council[22].

[22] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, pp. 1, ELI: http://data.europa.eu/eli/reg/2023/988/oj)

2026/0307 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) European standardisation is a key driver of the Union's competitiveness: standards facilitate the exchange of goods and services, foster interoperability, contribute to quality and consumer trust, and support technological development and the uptake of market innovation. By laying down technical or quality specifications with which current or future products, services, processes, systems or entities may comply, based on the consensus of market players and stakeholders, standards benefit both businesses and consumers. Standards are also an essential building block of the innovation process because they allow research and innovation results to spread and turn into market-ready solutions. Standardisation can provide a first-mover advantage in international technological races, by facilitating the adoption of new technologies and providing industrial ecosystems with a competitive edge.

(2) European standardisation plays a fundamental role in the functioning of the internal market, by providing common technical solutions that reduce transaction costs, foster economies of scale and promote effective competition. The development of standards and standardisation deliverables enable economic operators to place products and services on the market based on transparent and predictable technical frameworks, thereby increasing safety and value for consumers. In particular, standards have been at the core of the harmonisation of the internal market under the New Legislative Framework[2]. Furthermore, Regulation (EU) 1025/2012 of the European Parliament

[1] OJ C , , p. .

[2] Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93 (OJ L 218, 13.8.2008, pp. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj) and Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, pp. 82, ELI:

and of the Council[3] established the legal framework for European standardisation providing for the cooperation between the Union and the three European standardisation organisations listed in Annex I to that Regulation, namely the European Committee for Standardization ('CEN'), the European Committee for Electrotechnical Standardization ('CENELEC') and the European Telecommunication Standards Institute ('ETSI').

(3) European standardisation is essential for achieving the Union's industrial policy objectives, including the green transition, the digital transformation, industrial resilience and preparedness, and economic security. European standardisation supports the implementation of Union legislation and policies in areas such as decarbonisation, circularity, cybersecurity, artificial intelligence, critical technologies and sustainable resource use by giving effect to policy objectives through technical requirements and test methods that are applied consistently throughout the internal market.

(4) European standardisation also contributes to the Union's global competitiveness and strategic autonomy by supporting access to international markets and by enabling the Union to project its regulatory and industrial interests in global standard-setting processes, especially when established in coordination with the international standardisation bodies, namely the International Organization for Standardization ('ISO'), the International Electrotechnical Commission ('IEC') and the International Telecommunication Union ('ITU'), as well as with recognised standards development organisations and global standardisation partnerships in their sector of competence. Standards and standardisation deliverables can cover various issues, such as technical characteristics of products, services, processes, systems or entities, particularly in cases where compatibility and interoperability are essential.

(5) Standards and standardisation deliverables requested in accordance with this Regulation can support Union legislation and policies in several ways. They can be requested to give effect to essential requirements set out in Union harmonisation legislation under the New Legislative Framework and provide a presumption of conformity for product and services designed in accordance with such standards once their reference has been published in the *Official Journal of the European Union*. Such harmonised standards simplify the making of products and services available on the internal market and reduce compliance and conformity assessment costs for businesses, in particular for small and medium-sized enterprises ('SMEs'), startups and scaleups. They can also lay down test, measurement or calculation methods and criteria, such as for Regulation (EU) 2024/1781 of the European Parliament and of the Council[4] or for Regulation (EU) 2024/3110 of the European Parliament and of the

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http://data.europa.eu/eli/dec/2008/768(1)/oj), and Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) 765/2008 and (EU) 305/2011 (OJ L 169, 25.6.2019, pp. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

[3] Regulation (EU) 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 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj).

[4] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1781/oj).

Council[5] which specifies that compliance with such standard is mandatory, or more generally by translating legislative requirements into technical specifications, such as for Directive (EU) 2016/797 of the European Parliament and of the Council[6] or the proposed Regulation on public contracts and concessions[7]. In such cases, Union legislation not only lays down the legal value of the requested standards and standardisation deliverables but may also lay down the means by which their reference should be published in the *Official Journal of the European Union*, which includes referencing in an implementing act or a delegated act. Furthermore, standards and standardisation deliverables can be requested to support the implementation of the Union's industrial policy initiatives, as building blocks of competitive industrial ecosystems. This Regulation thus allows to provide for referenced standards and standardisation deliverables, which are standards and standardisation deliverables developed, revised or amended in response to a standardisation request and the reference of which has been published in the *Official Journal of the European Union*. The referenced standards and standardisation deliverables are either harmonised standards, harmonised standardisation deliverables or standards and standardisation deliverables in support of Union legislation and policies.

(6) The framework provided under Regulation (EU) No 1025/2012 is unfit to enable the European standardisation system to keep up with rapid technological changes and growing global competition. There are delays in the availability of harmonised standards, insufficient participation of relevant stakeholders and declining influence of Union stakeholders in international standardisation. Furthermore, the current framework is no longer aligned with the increasing number of Union legislation and policies that rely on standards, which include digital technologies, cybersecurity, artificial intelligence, clean tech and strategic value chains. Moreover, it is not fit to meet new challenges including the product-service convergence, the uptake of standardisation deliverables other than standards and the increasing relevance of standards development organisations other than the European standardisation organisations in certain specialised sectors. In addition, in light of the case-law of the Court of Justice of the European Union[8], the requirements for public access to harmonised standards need to be updated.

(7) The legal framework should be adapted to reflect those developments while maintaining a viable European standardisation system that is fit to address the new challenges in the field of standardisation. The Conclusions of the European Council of 19 March 2026[9] adopted the 'One Europe, One Market' roadmap to deepen the integration of the internal market and identified the revision of Regulation (EU) No 1025/2012 as a priority. This follows the Commission's Competitiveness Compass of January 2025[10] and the Single Market Strategy of April 2025[11] which identified the

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5 Regulation (EU) 2024/3110 of the European Parliament and of the Council of 27 November 2024 laying down harmonised rules for the marketing of construction products and repealing Regulation (EU) 305/2011 (OJ L, 2024/3110, 18.12.2024, ELI: http://data.europa.eu/eli/reg/2024/3110/oj).

6 Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (L 138, 26.5.2016, p. 44, ELI: http://data.europa.eu/eli/dir/2016/797/oj).

7 COM(2026) 590 final, 9.9.2026.

8 Judgment of 27 October 2016, James Elliott Construction Ltd v Irish Asphalt Ltd., C-613/14, EU:C:2016:821; Judgment of 5 March 2024, Public.Resource.Org and Right to Know v Commission, C-588/21 P, EU:C:2024:201.

9 EUCO 1/26, European Council meeting (19 March 2026) – Conclusions.

10 COM(2025) 30 final, 29.1.2025.

11 COM(2025) 500 final, 21.5.2025.

slow and unpredictable standardisation process in support of Union legislation and policies as one of the main barriers to the internal market. It is therefore necessary to improve the responsiveness of the European standardisation system and its ability to deliver standards in support of Union legislation and policies in a rapid, timely, inclusive and transparent way, while preserving the specificity of standardisation as a voluntary and market-driven tool. It is also necessary to ensure its long-term viability and ability to deliver standards that are accessible. The European standardisation system should also preserve its international influence in order to promote the Union's international competitiveness.

(8) This Regulation should thus lay down rules for the requesting, developing and referencing of standards and standardisation deliverables to support the implementation of Union legislation and policies. As common specifications pursue the same objectives as harmonised standards, this Regulation should provide a coherent framework for common specifications across Union legislation. Nevertheless, this Regulation should be without prejudice to other applicable sectoral rules laid down by Union legislation, including on common specifications and sectoral procedures to set standards or technical specifications. Additionally, a Union legal act might directly reference a standard or standardisation deliverable which has not been requested in accordance with this Regulation and provides such a standard or standardisation deliverable with a legal effect, insofar as it complies with requirements established by the case-law of the Court of Justice of the European Union[12].

(9) The legal framework set up by this Regulation should be applied while respecting the distribution of competences between the Union and Member States as laid down in the Treaties. In particular, the Commission should not, by requesting a standard or standardisation deliverable, affect the right to negotiate, conclude and enforce collective agreements and take industrial action in accordance with national legislation and practices which respect Union law. European standardisation organisations and designated standards development organisations should also refrain from conducting standardisation activities that could affect such rights. Furthermore, they are subject to competition law to the extent that they can be considered an undertaking or an association of undertakings within the meaning of Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

(10) Standards and standardisation deliverables requested by the Commission should comply with the World Trade Organization principles in the field of standardisation such as openness, transparency, and consensus as well as impartiality, independence from special interests and coherence. Consensus means seeking to take into account the views of all parties concerned but does not require unanimity. The process for the development of requested standards and standardisation deliverables should also guarantee a high level of inclusiveness by involving all relevant interested parties, including SMEs, civil society representatives, in particular those that are representing environmental, social and consumer interests, including women's rights organisations, equality bodies and organisations representing persons with disabilities, research and innovation stakeholders and public authorities. Such participation fosters a high level of market adoption as well as the high quality of standards and standardisation deliverables that reflect societal and market needs. Given the important role referenced standards and standardisation deliverables play in supporting the implementation of Union legislation and policies, they should be market-driven, so that the needs of

[12] Cf. Judgment of 21 April 2026, *Nederlandse Voedsel- en Warenautoriteit and Others v Stichting Rookpreventie Jeugd*, C-155/24, EU:C:2026:327.

economic operators and stakeholders directly or indirectly affected by such standards are duly taken into account, and reflect the public interest and the objectives of the Union legislation and policies they are supporting, such as competitiveness, innovation, sustainability, health and safety, security and economic security. Standards and standardisation deliverables should be technologically neutral, allowing fair competition between products, services or economic operators. Referenced standards and standardisation deliverables should also contribute to advancing the Union's values and fundamental rights, in particular accessibility for person with disabilities and gender equality. In order to ensure a high level of consumer protection and to contribute to equality between all consumers, they should take into account, where relevant, risks arising from products and services that can affect consumers differently on the basis of sex and gender, as recognised in the Commission's 2026–2030 Gender Equality Strategy[13].

(11) Requested standards and standardisation deliverables should be developed and adopted in compliance with the principles of transparency and accountability. European standardisation organisations and designated standards development organisations should thus make available to the public on their website the list of all stakeholders participating in their technical bodies in the development of each requested standard and standardisation deliverable, including organisations, associations, employers, groups and self-employed individuals, acting on their own behalf or on behalf of other organisations, and the interests they represent. In particular, European standardisation organisations and designated standards development organisations should ensure that the actual interests of stakeholders represented through client-intermediary relationships, such as through consultants or contractual ties, are included in the list of stakeholders made public on their website.

(12) Referenced standards and standardisation deliverables give technical expression to legal requirements and may produce legal effects. To ensure legal certainty, effective compliance and equal access to information necessary to comply with Union law, it is essential that such documents be made available to natural and legal persons within the Union free of charge, in a general, effective and non-discriminatory manner through a readable, searchable, printable and electronically accessible format. Economic operators from third countries having a legitimate interest would also have access to the standards through their authorised representative. European standardisation organisations and designated standards development organisations should therefore ensure that such access is provided without barriers, including mandatory pre-identification or subscription, and remains available after the reference has been withdrawn. Such access is to be in line with Directives (EU) 2016/2102 of the European Parliament and of the Council[14]. Access to referenced standards and standardisation deliverables requested under this Regulation can be limited to parts of the standards and standardisation deliverables which are necessary to comply with the requirements set out in the relevant Union legislation they support, provided that these parts constitute a self-standing document containing all necessary information. The same access should be granted to referenced standards and standardisation deliverables referenced under Regulation (EU) No 1025/2012. Access under this Regulation should be granted without prejudice to the potential copyrights that the European

[13] COM(2026) 113 final, 5.3.2026.

[14] Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1, ELI: http://data.europa.eu/eli/dir/2016/2102/oj).

standardisation organisations and designated standards development organisations may claim to have on the referenced standards and standardisation deliverables. European standardisation organisations and designated standards development organisations may implement appropriate digital rights management measures in view of the technological developments, in particular in Artificial Intelligence, which may facilitate the mass extraction or re-use of content contained in referenced standards or standardisation deliverables.

(13) The ongoing digitalisation of standardisation processes is an opportunity for the European standardisation system to both increase its responsiveness by accelerating the standardisation process through online standard development tools and to foster inclusiveness by decreasing the costs of participating in the standardisation process, particularly for SMEs, startups and scaleups, civil society stakeholders and research and innovation stakeholders. Digitalisation also has the potential to improve the quality of standards and standardisation deliverables, and to increase their use and take-up by market operators. So-called 'smart standards', where the content of the standards is complemented by additional data and information to facilitate their use and their integration in the business processes of market operators, have great potential to foster the Union's competitiveness. European standardisation organisations and designated standards development organisations should be encouraged to develop such smart standards and should ensure technical and semantic interoperability of the machine-readable formats of requested standards and standardisation deliverables and of their associated metadata, in order to facilitate their use by market operators, that may need to rely on several referenced standards and standardisation deliverables originating from different European standardisation organisation and designated standards development organisations.

(14) In order to foster the performance and accountability of the European standardisation system, the Commission should create an online platform (the 'EU Standards Platform') to make publicly available up-to-date information on requested standards and standardisation deliverables, in particular as regards the status of their development and referencing, and on common specifications. European standardisation organisations and designated standards development organisations should cooperate with the Commission to ensure that information on the EU Standards Platform is accurate and up to date to facilitate public scrutiny of the European standardisation system. The EU Standards Platform should be interoperable with relevant Union information systems and portals and should take into account relevant interoperability solutions developed or recommended under Regulation (EU) 2024/903[15].

(15) Free and unrestricted access to referenced standards and standardisation deliverables of European standardisation organisations risks having an impact on the revenues of national standardisation bodies that currently sell these documents. While national standardisation bodies and European standardisation organisations are developing alternative revenue sources, notably based on new services linked to 'smart standards', Member States and the Union may support funding the transition to new business models to strengthen the long-term financial viability of the European standardisation system. Furthermore, the Union may fund the participation of European stakeholder organisations designated under this Regulation which is essential for an inclusive

[15] 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) (OJ L, 2024/903, 22.3.2024, ELI: http://data.europa.eu/eli/reg/2024/903/oj).

standardisation process and contributes to balancing public and private interests. Funding opportunities under the Multiannual Financial Framework 2028-2034, including through the Single Market and Customs Programme[16], the European Competitiveness Fund[17] and the Horizon Europe Programme 2028-2034[18] and in accordance with the objectives and conditions set out in these programmes, may contribute to support the European standardisation activities, including to enhance the responsiveness of the European standardisation system, to promote its global relevance, to improve the usability and interoperability of standards and standardisation deliverables and more generally to foster the development of standards and standardisation deliverables that contribute to the Union's objectives. For those purposes, this Regulation should clarify that European standardisation organisations, national standardisation bodies, designated standards development organisations and European stakeholder organisations, may receive funding under the relevant Union programmes, including as potential designated beneficiaries in accordance with the conditions set out in these programmes.

(16) The responsiveness of the European standardisation system, in particular its ability to deliver standards and standardisation deliverables in time to facilitate market operators' compliance with Union legislation, depends on careful planning of future standardisation needs. The annual Union work programme on European standardisation should contribute to improve such strategic planning and coordination within the European standardisation system and should help to start standardisation work as soon as a need is identified. The work programme should also complement the Union's research and innovation policy and industrial strategy by identifying priority areas for pre-normative work, even before a specific standardisation need has been identified. It may be complemented by other tools allowing the early identification of standardisation needs or pre-normative work in support of Union legislation and policies, such as the European Rolling Plan on ICT standardisation.

(17) The European standardisation system is primarily organised by and for the relevant stakeholders within the three European standardisation organisations CEN, CENELEC and ETSI, based on national representation for CEN and CENELEC, and direct participation for ETSI. The European standardisation organisations have established strong connections with the industrial ecosystems within the Union. They cover a wide range of sectors, ensure a high-level of inclusiveness, quality, representation and influence of Union stakeholders, and contribute to further harmonising the internal market through the adoption of European standards that ensure that one single standard is available throughout the Union. They also ensure a high-level of alignment with international standardisation in their respective areas of expertise. The European standardisation organisations' processes are recognised and trusted by market operators, and they have built up expertise to deliver standards and standardisation deliverables to support the implementation of Union legislation and policies over the past decades. Thus, those European standardisation organisations should remain the main partners of the Union for developing requested standards and standardisation deliverables. The Commission should however be empowered to amend the list of European standardisation organisations set out in Annex I, to either designate a new European standardisation organisation to reinforce the European standardisation system in specific sectors, or to remove a European standardisation organisation from

16 COM(2025) 590 final, l3.09.2025.
17 COM(2025) 555 final, 16.07.2025.
18 COM(2025) 543 final, 16.07.2025.

Annex I, in particular if it no longer meets the requirements set out in this Regulation or it fails to perform at a sufficient level over a sustained period, as monitored on the basis of key performance indicators. As soon as the Commission identifies the underperformance of a European standardisation organisation, it should engage with that organisation to remedy the situation before removing the European standardisation organisation concerned from Annex I.

(18) The European standardisation system relies on the active involvement of the national standardisation bodies in the European standardisation organisations, in particular to guarantee that the interests of the Union are well represented when developing requested standards and standardisation deliverables. The participation of national standardisation bodies from candidate countries in European standardisation contributes to their alignement with the Union acquis and their gradual integration into the internal market. Member States should notify the Commission of the organisations they appoint as national standardisation bodies, and ensure, with the active cooperation of the European standardisation organisations, that at least one of their national standardisation bodies is a member of each European standardisation organisation. Member States should remain responsible for the effective implementation of this Regulation by their respective national standardisation bodies. Without affecting the important role played by stakeholders in preparing effective standards, the European standardisation organisations should ensure that formal decisions regarding requested standards and standardisation deliverables are taken exclusively by national standardisation bodies, in order to guarantee European decision-making for such standards and standardisation deliverables.

(19) In order to improve the performance of the European standardisation organisations, the Commission should monitor them based on key performance indicators to assess the speed of delivery and the quality of requested standards and standardisation deliverables, the inclusiveness of the European standardisation process and the international influence of the European standardisation system. To foster transparency and accountability, this assessment should be made publicly available on the EU Standards Platform.

(20) The cooperation between the Commission and the European standardisation organisations is essential for the performance of the European standardisation system. They should develop a close working relationship based on sincere cooperation, transparency and the open exchange of information. The European standardisation organisations should ensure the timely implementation of standardisation requests and the delivery of requested standards and standardisation deliverables in accordance with the objectives and timeframes laid down by the Commission. They should also ensure the participation of the Commission in their governance and technical bodies, in particular in their working groups and technical committees, so that the Commission might facilitate the development of requested standards and standardisation deliverables that comply with the requirements set out in the standardisation request and that satisfy the requirements set out in the Union legislation or the objectives set out in Union policies which they aim to cover. Furthermore, they should cooperate beyond requested standards and standardisation deliverables and foster the development of European standards and European standardisation deliverables that contribute to the Union’s competitiveness and core values. The European standardisation organisations play an important role in informing market operators on the availability of referenced standards and standardisation deliverables. They should strive to provide factual and up-to-date information to market operators, notably on the

status of standardisation activities conducted in response to standardisation requests. This would promote legal certainty and facilitate access to the internal market for market operators. In that context, the European standardisation organisations might cooperate for the development and maintenance of standards catalogues and serve as an information hub to their users.

(21) The European standardisation organisations play an essential role to harmonise the internal market by ensuring that national standards adopted by national standardisation bodies do not conflict with referenced European standards. Therefore, European standardisation organisations, national standardisation bodies and the Commission should engage in exchanging information on current and future standardisation activities. National standardisation bodies should withdraw national standards when a new standard covering the same scope is referenced. Such exchange of information should not prevent national standardisation bodies from complying with other obligations and commitments, in particular with Annex 3 to the Agreement on Technical Barriers to Trade[19].

(22) The quality, legitimacy and public acceptance of European standardisation depend on the appropriate and effective participation of all relevant stakeholders. The diverse participation of industry and SME experts, in particular experts from all the different segments of the value chains concerned, is essential for the rapid development of quality standards with a high-level of market relevance. Standards also serve as important tools for the competitiveness of SMEs, whose needs and interests may differ from those of larger undertakings. Therefore, their participation in the standardisation process should be ensured to increase their ability to contribute their innovation technologies to the standardisation process, to make standards more relevant and easy to use for SMEs, startups and scaleups, and to promote their market uptake by all relevant market operators.

(23) Standards have a broad societal impact: they influence citizens' safety and well-being, the environment, workers' safety and working conditions, the inclusion of persons with disabilities, equality, in particular gender equality, as well as fundamental rights and other areas of public interest. Therefore, European standardisation should represent social, environmental and consumer interests so that standards respect Union values, meet societal needs, reflect market realities and support a resilient, innovative and socially balanced Union economy. The active contribution of stakeholders representing such interests is a distinctive factor of the European standardisation system and contributes to the adoption of standards that are both market-relevant and support Union policy objectives and values. The European standardisation system should take into account the 2004 United Nations Convention on the Rights of Persons with Disabilities and should facilitate the participation of people with disabilities, in line with the requirements set out in Directive (EU) 2019/882[20] of the European Parliament and of the Council. In particular, it is necessary for the European standardisation organisation to facilitate the accessibility to standardisation activities for persons with disabilities.

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19 Approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ L 336, 23.12.1994, p. 1).

20 Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, pp. 70, ELI: http://data.europa.eu/eli/dir/2019/882/oj).

(24) Standards are also a key part of the innovation value chain and facilitate the diffusion of new technologies. Standardisation activities can bridge research with market and societal uptake and act as a valorisation channel, as recognised in the Guiding principles for knowledge valorisation[21] and the Code of practice on standardisation in the European Research Area[22]. Therefore, research and innovation stakeholders, such as researchers, academics, research centres, startups and scaleups, and stakeholders from the open-source community, should be actively involved in European standardisation, because their participation enhances the technological relevance, quality and neutrality of standards and promotes the uptake and valorisation of research results with clear standardisation potential. European standardisation activities should in particular build on relevant research and innovation generated through the implementation of Union funded research projects and other research and innovation actions, as well as owned by research and technology infrastructures which have been funded by the Union. With the digitalisation of society and the evolution of new technologies, open-source software and open-source solutions play an ever-important role in supporting innovation. Open source and open standards are complementary instruments for fostering competition, interoperability, transparency, technological resilience and digital sovereignty within the Union. Open source can reduce vendor lock-in and dependencies, support collaboration across borders and sectors, facilitate the efficient re-use of digital solutions, including in the public sector and contribute to security and resilience. In line with the EU Open Source Strategy[23], it is important to actively support the participation of open source organisations, such as open source software stewards and open source communities in standardisation activities, including as implementing parties.

(25) Public authorities, including market surveillance authorities, play an important role in ensuring that standards and standardisation deliverables developed following a standardisation request from the Commission are fit for regulatory purposes and capable of supporting effective implementation and enforcement of Union legislation. Member States should therefore, where appropriate, encourage the participation of such authorities in national and European standardisation activities concerning standards and standardisation deliverables requested by the Commission. Such involvement helps to align technical specifications and legal requirements, while also supporting regulatory learning from practical experience. It also reduces the risk of non-compliance or rejection of the delivered standards and standardisation deliverables. The Commission research facilities and relevant Union agencies also help ensuring that Union public policy reflects and supports research and innovation and the advancement of science as a basis for public policy. It is thus important that they are also involved in the standardisation activities in support of Union legislation and policies, and European standardisation organisations should ensure their free access to the relevant standards and standardisation deliverables to conduct this work.

(26) The coordination and representation of SMEs and societal interests, which may vary across the Union, are a challenge for the European standardisation process. In order to facilitate the coordination of such interests and to guarantee their effective representation, the Commission should designate European stakeholder organisations

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21 Council Recommendation (EU) 2022/2415 of 2 December 2022 on the guiding principles for knowledge valorisation.

22 Commission Recommendation (EU) 2023/498 of 1 March 2023 on a Code of Practice on standardisation in the European Research Area.

23 COM(2026) 503 final, 03.06.2025.

representing SMEs, consumers, environmental interests and social interests based on objective criteria and a transparent and non-discriminatory process. The selection should take place at least every four years to ensure their ability to build up the necessary skills and competences. The organisation representing the interests of consumers should contribute to ensure that standards reflect the lived experiences and needs of the entire population through the participation of equality stakeholders, in particular women or persons with disabilities, whose interests are underrepresented in the standardisation process. The representation of social interests and social stakeholders in European standardisation activities particularly refers to the activities of organisations and parties representing employees and workers' basic rights, for instance trade unions. European standardisation organisations should actively involve those European stakeholder organisations at each stage of the standardisation process of the requested standards and standardisation deliverables relevant to the interests they represent. This obligation does not necessarily entail any voting rights for such stakeholders. However, European standardisation organisations should do their utmost to take the comments of such organisations into account and to explain, where relevant, how they have been taken into consideration. Designated standards development organisations should also ensure that these organisations can effectively contribute to the development of requested standards and standardisation deliverables.

(27) National standardisation bodies are essential to foster the effective participation in the European standardisation system for relevant stakeholders. Barriers to participation are generally lower at national level, due to lower costs of participation, the absence of linguistic barriers as well as better awareness and familiarity of stakeholders with the national standardisation process. To achieve a high-level of participation and inclusiveness of the European standardisation system, national standardisation bodies should ensure the effective participation of SMEs, consumer organisations, environmental and social stakeholders, including women's rights organisations, equality bodies, organisations representing persons with disabilities, research and innovation stakeholders and public authorities. As the costs and time required for standardisation are key barriers to participation for these stakeholders, national standardisation bodies should facilitate the participation in their standardisation activities without mandatory membership. They should also provide such stakeholders with free access or reduced rates. Free access to draft standards and draft standardisation deliverables is particularly important to allow timely and informed participation and to improve the legitimacy, inclusiveness and practical relevance of the resulting standards.

(28) The Commission should consult European standardisation organisations on new standardisation needs that may trigger a standardisation request, for instance needs identified in the annual Union work programme on European standardisation, to allow them to indicate their ability to accept the standardisation request and to deliver high-quality standards or standardisation deliverables in a timely manner. Based on the consultation, the Commission should make an informed assessment of the capacity and preparedness of European standardisation organisations to deliver the requested standards and standardisation deliverables, based on the activities they are carrying out in that area, the technical expertise that they are able to mobilise and the likely duration of the process. The consultation should also contribute to identifying possible specificities in terms of stakeholder participation, inclusiveness requirements, restriction of participation to Union actors or the identification of existing relevant technical specifications or standards.

(29) When, following the consultation of European standardisation organisations, the Commission has concluded that one or more European standardisation organisations would be best placed to develop, revise or amend the requested standards or standardisation deliverables, it should address a standardisation request to them. To improve the overall responsiveness of the European standardisation system, the Commission should endeavour to adopt a standardisation request within 12 months following receipt of the reply of the European standardisation organisations to the consultation. The standardisation request should lay down with sufficient precision the requirements concerning the content to be met by the requested standards and standardisation deliverables and indicate a deadline for the delivery of each relevant standard and standardisation deliverable. The standardisation request may also include provisions regarding the periodic revision of the requested standards or standardisation deliverables within the date of expiry of the request, in particular to take into account the evolution of technologies. The standardisation request may set out the main procedural steps, and their required timing, to be undertaken by the European standardisation organisations for the timely delivery of the request, such as setting up a technical committee to work on the requested standard or standardisation deliverable, concluding adequate cooperation agreements with other standards development organisations that would be identified in the request as well as intermediary procedural steps linked to the European standardisation organisations' internal procedures, such as the date for enquiry or formal votes. The Commission should publish draft standardisation requests on the EU Standards Platform to allow for the European standardisation organisations, the European stakeholder organisations and the relevant European sectoral stakeholders to submit their comments, in particular experts from the Member States.

(30) There may be areas where the time required to deliver a harmonised standard could be too long and slow down market uptake, for instance for digital products and services with shorter lifecycle and a high level of innovation. The Commission should be able in such cases to request European standardisation organisations to deliver a harmonised standardisation deliverable covering the relevant essential requirements necessary for providing a presumption of conformity, as an intermediate step toward a harmonised standard. Such deliverables should be of high quality and based on an inclusive, open and transparent standardisation process. However, they should not necessarily have reached the same level of consensus or consultation as a fully fledged harmonised standard. The Commission should publish the reference of the harmonised standardisation deliverable if it complies with all the essential requirements it aims to cover, providing a presumption of conformity for the products and services based on such a harmonised standardisation deliverable. The European standardisation organisations should continue to develop the corresponding harmonised standard, which, once delivered, should replace the harmonised standardisation deliverable to ensure that there is no conflicting standard or standardisation deliverable providing a presumption of conformity for a given product or service.

(31) The Commission may also, in order to increase the speed of the standardisation process and better align requested standards and standardisation deliverables with state of the art technical specifications, specify in its standardisation request an obligation for European standardisation organisations to take into account identified existing technical specifications or standards. These could be technical specifications or standards from other standards development organisations, or technical specifications developed by Union bodies or agencies or developed within European initiatives like the European Interoperability Framework or semantic interoperability community

(SEMIC) specifications. European standardisation organisations should be responsible for the agreements with standards development organisations, Union bodies and agencies that develop these standards or technical specifications, where necessary, and ensure that the delivered standards or standardisation deliverables based on existing technical specifications or standards comply with the obligations laid down in this Regulation. In this regard, European standardisation organisations should build and expand their current initiatives to evaluate and integrate such external standards and technical specifications into their catalogue.

(32) The Commission should also be able to include specific requirements for participation and inclusiveness in its standardisation request. For instance, for requested standards and standardisation deliverables that support accessibility or that may have an impact on fundamental rights, it may be essential to ensure the active and effective participation of stakeholders which might not be usually involved in the European standardisation process to ensure that they are aligned with the Union's values. Furthermore, the standardisation request may introduce specific requirement as regards participation in the development of standards and standardisation deliverables relating to Union strategic assets, interests, autonomy, security or economic security, or where international standards might not be fit for the Union interests. In such cases, it may be appropriate that the European standardisation process is restricted to European actors or actors that share the interests of the Union. Therefore, the Commission may specify that only certain types of stakeholders can participate in the standardisation process or that the European standardisation process can diverge from existing international standards or international standards that are under development, in order to protect the Union's strategic autonomy and its strategic interests.

(33) A European standardisation organisation that has accepted a standardisation request should regularly report to the Commission on the activities it has undertaken and the progress it has achieved. It should submit such a report every year but it should be possible for the standardisation request to specify a shorter reporting frequency. The European standardisation organisation should make available to the Commission the relevant drafts documents in response to the request and should duly take into account comments from the Commission to foster compliance. Where the European standardisation organisation is unable to deliver the requested standards and standardisation deliverables within the deadlines set out in the request, and the Commission considers that the best option is to continue the implementation of the standardisation request, it may amend the deadlines or expiry dates using a simplified procedure, without having to formally re-consult stakeholders. Where several European standardisation organisations have accepted a standardisation request, they should establish a structured mode of collaboration to ensure cross-participation of experts and the efficient implementation of the standardisation request. European standardisation organisations that have accepted a standardisation request should be responsible for complying with the requirements set out in the request. This includes situations where the implementation involves cooperating with other organisations, for instance liaison organisations, or with international standardisation bodies, in particular where the development of the requested standards and standardisation deliverables takes place fully or partly at the international level due to an agreement between the European standardisation organisation and an international standardisation body.

(34) Standards and standardisation deliverables developed in response to a standardisation request should be delivered to the Commission as soon as they are adopted by the

European standardisation organisations. The Commission should assess the compliance of the delivered standard or standardisation deliverable with the requirements it aims to cover and with the procedural and content requirements set out in the standardisation request. The European standardisation organisations should cooperate with the Commission to facilitate this assessment, notably by ensuring that the Commission has all the relevant documents and necessary information including, where relevant, normative references. The Commission should conduct the assessment within six months from the delivery of the requested standard or standardisation deliverable to avoid uncertainties whereby a requested standard or standardisation deliverable adopted by European standardisation organisations is available to market operators, while its legal effect might not yet be established.

(35) When the Commission has assessed that the delivered standard or standardisation deliverable satisfies the essential requirements, set out in Union legislation, which it aims to cover, or where appropriate, the objectives of the relevant Union policies, and complies with the requirements set out in the request, it should publish a reference of that standard or standardisation deliverable without delay in the *Official Journal of the European Union.* That reference allows market operators to rely on such referenced standard or standardisation deliverable to either benefit from a presumption of conformity with Union legislation, or from other potential legal effect set out in the corresponding Union legislation. If the Commission concludes that the quality of a delivered standard or standardisation deliverable is not adequate, it may reject it or publish its reference with restrictions, indicating the requirements that are not covered and for which the standard cannot provide a presumption of conformity or means to comply with the relevant Union legislation. The Commission should exercise discretion to assess the compliance with procedural requirements laid down in the standardisation request, and should balance whether non-compliance with procedural requirements, for instance late delivery, are sufficient to justify not referencing the standard or standardisation deliverable.

(36) In order for the European standardisation system to respond effectively to evolving technological and policy needs, especially where the necessary expertise might not exist within the European standardisation organisations, the Commission should be able to address standardisation requests to other standards development organisations, which are not national nor international standardisation bodies. These standards development organisations should be designated based on objective criteria ensuring their ability to deliver a highly inclusive standardisation process which reflects European interests. The Commission should only designate standards development organisations that are able to comply with the principles for European standardisation set out in this Regulation and with the best standardisation practices. Designated standards development organisations should in particular ensure the openness, transparency and inclusiveness of their standardisation process. They should comply with all the specific requirements set out in this Regulation, in particular the free and unrestricted access to referenced standards and standardisation deliverables, the transparency and inclusiveness of the standardisation process and the publicity of interests represented, the effective participation of Union stakeholders including research and innovation stakeholders, SMEs, startups and scaleups, consumers, environmental and social stakeholders, notably where relevant women's rights organisations, equality bodies, and organisations representing persons with disabilities. The Commission should pay particular attention to the ability of the designated standards development organisations to facilitate the participation of European stakeholder organisations and European stakeholders. Designated standards

development organisations should ensure that Union interests are effectively taken into account where they are represented. Open source organisations may develop technical specifications that meet the needs of the Union and could be designated as standards development organisations as long as they comply with the criteria set out in this Regulation.

(37) In order to ensure that addressing a standardisation request to designated standards development organisations complements the European standardisation system rather than fragments it, appropriate safeguards should apply concerning transparency, information-sharing and cooperation between designated standards development organisations and the European standardisation organisations. The designated standards development organisations should maintain a high level of transparency in their standardisation activities similar to the level ensured by European standardisation organisations to avoid duplicating work, prevent inconsistencies between their respective standards and standardisation deliverables and protect the functioning of the internal market. They should provide access to the draft standards and standardisation deliverables developed pursuant to a standardisation request to the European standardisation organisations upon their request and should duly take account of comments addressing issues of coherence between the draft standards and standardisation deliverables and relevant referenced standards and standardisation deliverables, especially as regards any comments indicating that a draft requested standard or standardisation deliverable may adversely affect the internal market by conflicting with existing relevant referenced standards or standardisation deliverables.

(38) The Commission may address a standardisation request to designated standards development organisations when the European standardisation organisations have indicated during the consultation that they would not accept a standardisation request, or when the Commission has assessed that, based on their consultation, the European standardisation organisations are not in a position to deliver timely and high-quality standards and standardisation deliverables, notably when the scope of the standardisation request and the relevant technical expertise clearly lies with the competences of designated standards development organisations. The Commission may also address a standardisation request to designated standards development organisations when European standardisation organisations fail to deliver the requested standard or standardisation deliverable or to appropriately comply with the standardisation request. Such a decision should be based on the information available from the European standardisation organisations and carefully balance the impact of interrupting the activities of the relevant European standardisation organisations to develop the requested standards or standardisation deliverables with the potential benefits of addressing the request to designated standards development organisations. In such cases, the Commission should withdraw the standardisation request to the European standardisation organisations to prevent the existence of different standards that address the same essential requirements.

(39) As referenced standards or standardisation deliverables developed by designated standards development organisations have the same status as referenced standards and standardisation deliverables developed by the European standardisation organisations, the process and requirements for addressing, implementing and assessing standardisation request to designated standards development organisations should be similar as for European standardisation organisations. However, given the particularities of requesting a standard or standardisation deliverable to designated standards development organisations, it is appropriate that all standardisation requests

to designated standards development organisations should be adopted by the Commission by means of implementing acts in accordance with the examination procedure. The Commission may simultaneously designate a standards development organisation and address a standardisation request to it. The Commission should assess the coherence of the delivered standards or standardisation deliverables with the relevant referenced standards and standardisation deliverables to prevent conflicts between referenced standards and standardisation deliverables.

(40) This Regulation provides for a horizontal framework that will promote the timely development of harmonised standards by European standardisation organisations and by designated standards development organisations. However, where no such harmonised standard exists or such a standard is not expected to be delivered within a reasonable period, the Commission should be able to adopt common specifications by implementing acts that provide a means to comply with the essential requirements set out in relevant Union legislation. Compliance with common specifications should remain voluntary for businesses, which may rely on them to benefit from a presumption of conformity or choose other appropriate methods to demonstrate compliance with Union requirements. The Commission would ensure a highly inclusive process to develop common specifications, and should consult relevant European stakeholders, in particular the appropriate expert groups set out to support the implementation of corresponding Union legislation. The Commission should also leverage, where appropriate, the existing standardisation work conducted by European standardisation organisations or designated standards development organisations, in the preparation of common specifications. When European standardisation organisations or designated standards development organisations deliver a standard that covers the same requirements as those covered in adopted common specifications, the Commission should assess such a standard without delay. If it satisfies the essential requirements which it aims to cover and complies with the standardisation request, the Commission should withdraw the common specifications at the same time it publishes a reference to that harmonised standard.

(41) Member States, the European Parliament and the Commission, notably following information received from market surveillance authorities, should be able to notify that they consider a referenced standard or standardisation deliverable or common specification does not satisfy the requirements it aims to cover. To promote legal certainty for businesses, it is essential that such safeguard notifications are resolved as fast as possible. It is thus appropriate that, if there is no objection to the notification, their reference is restricted or withdrawn, or the common specification repealed. Nevertheless, when one or more Member States, the European Parliament or the Commission objects, the Commission should only take its decision after consulting all involved parties and assessing the information provided by the Member States or the European Parliament.

(42) To foster legal certainty for businesses, it is important that the references to standards and standardisation deliverables are closely aligned with the portfolio of standards and standardisation deliverables managed by European standardisation organisations and designated standards development organisations. When such organisations engage in the process of amending, revising or withdrawing a referenced standard or standardisation deliverable, for instance because they consider that it is no longer in line with the state of the art or with market requirements, they should notify the Commission without delay so that the Commission could, if appropriate, update or withdraw the reference to the amended, revised or withdrawn standards or

standardisation deliverables. The Commission may also withdraw a reference or repeal a common specification on its own initiative, for instance when it considers that it no longer meets the state of the art.

(43) Given the close links between the European and international standardisation systems, and the importance of standards for international trade and competitiveness, the European standardisation system should promote coherence with international standardisation while safeguarding Union interests, values and policy objectives. In line with international practices, European standards and European standardisation deliverables should align with international standards to foster international trade and the Union's competitiveness. While cooperation and alignment with their mirror international standardisation bodies is important for the European standardisation organisations, it is appropriate to allow for exceptions where draft or existing international standards would be an ineffective or inappropriate means to fulfil the Union's policy objectives. The Commission should therefore carefully assess the alignment with international standards and its impact on the Union's competitiveness and strategic autonomy.

(44) In order to strengthen the Union's global presence in standardisation, the European standardisation system should facilitate a coordinated Union approach in international standardisation, in particular in emerging and strategic technologies, in light of increasing international competition and strategic use of standards by other global actors. The Union should promote cooperation, including through relevant experts group, between European standardisation organisations, international standardisation bodies and other standard development organisations when relevant, in particular recognised standard development organisations in their sector of competence.

(45) To coordinate standardisation activities, relations with European standardisation organisations and designated standards development organisations and promote a Union approach in international standardisation, the Commission should create a Centre of Excellence on European Standardisation whose mission should be to ensure an effective implementation of this Regulation and a well-functioning European standardisation system. The Centre of Excellence, which might be led by a Chief Standardisation Officer, should serve as a coordinating hub for stakeholders who contribute to the efficient development of referenced standards and standardisation deliverables as well as of common specifications. It should in particular ensure the cooperation with the European standardisation organisations and the identification and cooperation with designated standards development organisations. The Centre of Excellence should also ensure the coordination between experts from the Commission, relevant Union agencies and public authorities from Member States to strengthen the network of European experts active in standardisation, at both European and international levels. The Centre of Excellence should also contribute to improve the anticipation of standardisation needs by better articulating research and innovation policy and standardisation activities, notably pre-normative activities.

(46) In order to foster the performance of the European standardisation system, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to Annex I to this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13

April 2016 on Better Law-Making[24]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(47) The Committee established pursuant to this Regulation should assist the Commission in matters related to the implementation of this Regulation. In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council[25]. The examination procedure should be used for adopting standardisation requests addressed to designated standards development organisations and for standardisation requests addressed to European standardisation organisations when they include specific requirements introduced by this Regulation, namely the request for harmonised standardisation deliverables, the restriction of participation to the standardisation process to actors representing Union interests and restricting requirements as regards the usual cooperation with international standardisation bodies. For all other standardisation requests addressed to European standardisation organisations, in order to accelerate the standardisation process, it is appropriate for the Commission to adopt them by way of implementing act without a committee procedure, as national interests are represented in the European standardisation organisations and Member States can take part in the public consultation for such requests. The examination procedure should be used for adopting common specifications.

(48) Since the objectives of this Regulation, namely to increase the responsiveness of the European standardisation system, ensure a financially viable and inclusive European standardisation system and consolidate the Union's influence in international standardisation, cannot be sufficiently achieved by the Member States alone, due to the harmonisation effect of referenced standards and standardisation deliverables, but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(49) In the interest of clarity and legal certainty, Regulation (EU) No 1025/2012 should be repealed and replaced by this Regulation. Additionally, in the interests of coherence, Article 48 of Regulation (EU) 2023/988 of the European Parliament and of the Council[26] should be repealed.

(50) This Regulation should apply six months after its entry into force,

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24 OJ L 123, 12.5.2016, p. 1.

25 Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, pp. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

26 Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, pp. 1, ELI: http://data.europa.eu/eli/reg/2023/988/oj).

HAVE ADOPTED THIS REGULATION:

Chapter 1
General provisions

Article 1

Subject matter

This Regulation lays down rules with regard to:

(a) the requesting, development and referencing of harmonised standards, harmonised standardisation deliverables, and standards and standardisation deliverables in support of Union legislation and policies;

(b) the cooperation between European standardisation organisations, national standardisation bodies, designated standards development organisations, Member States and the Commission;

(c) the participation of European stakeholders in European standardisation;

(d) the adoption of common specifications.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'standard' means a technical specification, adopted by a standards development organisation, for repeated or continuous application;

(2) 'standardisation deliverable' means a technical specification other than a standard, adopted by a standards development organisation, for repeated or continuous application;

(3) 'technical specification' means a document that sets out technical requirements that are to be fulfilled by a product, service, process, system or entity;

(4) 'requested standard and standardisation deliverable' means a standard and standardisation deliverable developed, revised or amended in response to a standardisation request;

(5) 'referenced standard and standardisation deliverable' means a harmonised standard, a harmonised standardisation deliverable or a standard and standardisation deliverable in support of Union legislation or policies;

(6) 'harmonised standard' means a standard developed, revised or amended in response to a standardisation request, the reference of which has been published in the *Official Journal of the European Union*, and the conformity with which provides for a presumption of conformity with the requirements, set out in the relevant Union legislation, which it aims to cover;

(7) 'harmonised standardisation deliverable' means a standardisation deliverable developed, revised or amended in response to a standardisation request, the reference of which has been published in the *Official Journal of the European*

Union, and the conformity with which provides for a presumption of conformity with the requirements, set out in the relevant Union legislation, which it aims to cover, and which is intended to be replaced by a harmonised standard;

(8) 'standard and standardisation deliverable in support of Union legislation or policies' means a standard and standardisation deliverable developed, revised or amended in response to a standardisation request, that does not aim at providing presumption of conformity with requirements set out in Union legislation, and the reference of which has been published in the *Official Journal of the European Union*;

(9) 'common specification' means a technical specification adopted by the Commission, the conformity with which provides for a presumption of conformity with the requirements, set out in the relevant Union legislation, which it aims to cover;

(10) 'European standardisation organisation' means an organisation listed in Annex I;

(11) 'national standardisation body' means a standardisation body notified to the Commission by a Member State in accordance with Article 11;

(12) 'standards development organisation' means an organisation which develops and adopts standards and standardisation deliverables in line with internationally recognised principles on standardisation;

(13) 'designated standards development organisation' means a standards development organisation, other than a European standardisation organisation, to which the Commission may address a standardisation request;

(14) 'European stakeholder organisations' means the organisations representing micro, small and medium-sized enterprises ('SMEs'), as defined in Commission Recommendation 2003/361/EC[27], consumers, environmental and social interests to foster the inclusiveness of the European standardisation system, as designated in accordance with this Regulation;

(15) 'European standardisation system' means the framework of actors and processes involved in the development of referenced standards and standardisation deliverables, and common specifications, to support Union legislation and policies, in particular the European standardisation organisations, the designated standards development organisations, the European stakeholder organisations, national standardisation bodies, Member States, the Commission as well as stakeholders taking part in the standardisation process;

(16) 'standardisation request' means a decision of the Commission addressed to a European standardisation organisation or a designated standards development organisation requesting such an organisation to develop, revise or amend standards or standardisation deliverables;

(17) 'national standard' means a standard adopted by a national standardisation body;

[27] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

(18) ‘European standard’ means a standard adopted by a European standardisation organisation;

(19) ‘European standardisation deliverable’ means a standardisation deliverable adopted by a European standardisation organisation;

(20) ‘international standard’ means a standard adopted by an international standardisation body;

(21) ‘international standardisation body’ means the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) or the International Telecommunication Union (ITU).

Chapter 2
Principles of European standardisation in support of Union legislation and policies

Article 3

Principles of European standardisation

1. Referenced standards and standardisation deliverables shall be developed in compliance with this Regulation and in line with international good practices and principles for the development, adoption and use of standards and standardisation deliverables including the principles of openness, transparency, consensus, technological neutrality and inclusiveness.

2. Referenced standards and standardisation deliverables and common specifications shall take into account the economic and public interests and the objectives of Union legislation and policies which they are supporting, in particular economic competitiveness, innovation, societal needs, including climate and environmental sustainability, health and safety, security and economic security.

Article 4

Transparency of the development of requested standards and standardisation deliverables

European standardisation organisations and designated standards development organisations shall make public on their website, for each requested standard and standardisation deliverable:

(a) the list of organisations and stakeholders participating in their technical bodies tasked with its development, revision or amendment;

(b) the interests that those organisations and stakeholders represent.

Article 5

Access to referenced standards and standardisation deliverables

1. European standardisation organisations and designated standards development organisations shall provide unrestricted free online access to referenced standards

and standardisation deliverables, including any amendments, corrigenda and referenced revisions thereof, in any languages that are authentic for such referenced standards and standardisation deliverables.

2. European standardisation organisations and designated standards development organisations shall ensure that referenced standards and standardisation deliverables are available in a readable, searchable, printable, and electronically accessible format and that they remain continuously available to the public, even after their references have been withdrawn from the *Official Journal of the European Union*.

3. European standardisation organisations and designated standards development organisations shall ensure that any arrangements concerning referenced standards and standardisation deliverables do not prevent or restrict compliance with the obligations laid down in this Article.

Article 6

Digitalisation of standard development

1. European standardisation organisations and designated standards development organisations shall endeavour to develop requested standards and standardisation deliverables using digital development tools and in a structured machine-readable format, suitable for automated processing.

2. European standardisation organisations and designated standards development organisations shall ensure the technical and semantic interoperability of the machine-readable formats of requested standards and standardisation deliverables and of their associated metadata.

Article 7

EU Standards Platform

1. The Commission shall establish, manage and maintain a digital platform (the 'EU Standards Platform') to:

   (a) list the referenced standards and standardisation deliverables, as well as common specifications;

   (b) inform users on how to access referenced standards and standardisation deliverables pursuant to Article 5;

   (c) provide information on standardisation requests and the status of their implementation;

   (d) provide information on the performance of the European standardisation system;

   (e) provide other relevant information regarding the European standardisation system.

2. European standardisation organisations and designated standards development organisations shall make available to the Commission, in a timely, structured and machine-readable manner, the relevant information on their standardisation activities under this Regulation.

Article 8

Union financing of the European standardisation system

1. The Union and the Member States may contribute to the financial sustainability of the European standardisation system, including the standardisation activities of the European standardisation organisations and national standardisation bodies to develop requested standards and standardisation deliverables, as well as to the financing of other standardisation activities in support of Union objectives.

2. The Union may grant financial support to any of the following bodies in accordance with the objectives and conditions of the relevant Union funding programmes:

   (a) European standardisation organisations;

   (b) designated standards development organisations;

   (c) European stakeholder organisations;

   (d) national standardisation bodies.

3. By 31 March each year, European standardisation organisations shall provide the Commission with the relevant information on their financial sustainability linked to their activities for requested standards and standardisation deliverables.

Article 9

Annual Union work programme on European standardisation

1. Each year, the Commission shall adopt a work programme on European standardisation.

2. The annual Union work programme referred to in paragraph 1 shall contain the following information:

   (a) the new standardisation requests that the Commission intends to adopt in the following year;

   (b) the standardisation areas for which the Commission may adopt standardisation requests in the following years, notably based on the Commission's work programme and relevant Union strategies;

   (c) the policy areas requiring pre-normative work, notably based on the Union research and innovation priorities;

   (d) any additional information relevant to identifying strategic priorities for European standardisation.

3. In cases of urgency, the Commission may adopt standardisation requests without prior indication in the annual Union work programme referred to in paragraph 1.

4. Before adopting the annual Union work programme referred to in paragraph 1, the Commission shall publish the draft annual Union work programme on the EU Standards Platform. Member States, the European standardisation organisations, designated standards development organisations, European stakeholder organisations, industry and research and innovation stakeholders may provide their opinion within one month following the publication of the draft annual Union work programme.

Chapter 3
Standards and standardisation deliverables from European standardisation organisations

SECTION 1
EUROPEAN STANDARDISATION ORGANISATIONS

Article 10

Designation of the European standardisation organisations

1. The European standardisation organisations are listed in Annex I.
2. The Commission is empowered to adopt delegated acts in accordance with Article 39 to amend Annex I to designate new European standardisation organisations or to withdraw a European standardisation organisation.
3. The Commission may designate a European standardisation organisation if it meets all of the following requirements:
   (a) it is established in the Union;
   (b) it has at least one national standardisation body of each Member State among its members;
   (c) it is able to comply with the requirements set out in this Regulation.
4. The Commission may withdraw a European standardisation organisation from Annex I where:
   (a) it no longer complies with the requirements set out in this Regulation; or
   (b) based on the monitoring of the key performance indicators referred to in Article 13, it no longer ensures a sufficient level of performance in implementing this Regulation.

Article 11

National standardisation bodies

1. Each Member State shall appoint at least one national standardisation body established in the Union and shall ensure that at least one national standardisation body is a member of each European standardisation organisation.
2. Member States shall inform the Commission of the national standardisation bodies they have appointed, indicating the European standardisation organisations of which they are a member. They shall inform the Commission without delay of any changes to the appointed national standardisation bodies.
3. The Commission shall publish and maintain the list of national standardisation bodies, indicating the European standardisation organisations of which they are a member, on the EU Standards Platform.
4. Member States shall ensure that national standardisation bodies comply with their obligations under this Regulation.

Article 12

European decision-making for requested standards and standardisation deliverables

Irrespective of other advisory opinions, each European standardisation organisation shall ensure that all of the following decisions concerning requested standards and standardisation deliverables are taken exclusively by representatives of the national standardisation bodies within the competent decision-making body of that organisation:

(a) decisions on the acceptance and refusal of a standardisation request;

(b) decisions on the acceptance of new work items needed for fulfilling a standardisation request;

(c) decisions on the adoption, revision, amendment, and withdrawal of requested standards and standardisation deliverables.

Article 13

Key performance indicators and performance management of European standardisation organisations

1. The Commission shall monitor the performance of the European standardisation organisations relating to the implementation of this Regulation on the basis of key performance indicators supporting the regular assessment of the following:

   (a) the speed and timeliness of European standardisation organisations to deliver requested standards and standardisation deliverables;

   (b) the quality of the requested standards and standardisation deliverables delivered by European standardisation organisations;

   (c) the inclusiveness of the standardisation process of European standardisation organisations for requested standards and standardisation deliverables;

   (d) the cooperation between European standardisation organisations and national standardisation bodies;

   (e) the international influence of the European standardisation system;

   (f) any other elements relevant for evaluating the performance of the European standardisation organisations.

2. The Commission, after consulting the European standardisation organisations, shall adopt, by means of implementing acts in accordance with the advisory procedure referred to in Article 40(2), and publish, on the EU Standards Platform, the target value, the frequency and the methodology for the calculation of the key performance indicators referred to in paragraph 1 of this Article.

3. The Commission and the European standardisation organisations shall ensure that the values of the key performance indicators referred to in paragraph 2 are made public and regularly updated on the EU Standards Platform.

4. Each European standardisation organisation shall send an annual report on the implementation of this Regulation to the Commission by 31 January each year, covering the preceding calendar year. In that report, they shall provide details on the key performance indicators established in accordance with paragraph 2. Each European standardisation organisation shall publish its report on its website each year.

5. The Commission and European standardisation organisations shall hold a high-level structural dialogue meeting at least twice a year, to review the key performance indicators and to foster performance and cooperation between the Commission and the European standardisation organisations.

Article 14

Cooperation between the Commission and the European standardisation organisations

1. The Commission and the European standardisation organisations shall cooperate closely and in a spirit of sincere cooperation as regards the preparation, implementation and assessment of standardisation requests.
2. The cooperation shall be based on transparency, the timely exchange of information and appropriate consultation between the Commission and the European standardisation organisations.
3. European standardisation organisations shall allow for the participation of the Commission in their governance decision bodies and in their technical bodies.

Article 15

Transparency of work programmes of European standardisation organisations and national standardisation bodies

1. At least once a year, each European standardisation organisation and each national standardisation body shall adopt its work programme. That work programme shall contain information on the standards and standardisation deliverables which the European standardisation organisation or national standardisation body intends to develop, revise or amend, is developing, revising or amending, or has adopted, revised or amended during the period of the preceding work programme, except where those standards or standardisation deliverables are transpositions of European standards or European standardisation deliverables.
2. The work programme shall indicate for each standard and each standardisation deliverable:
   (a) the subject matter;
   (b) the stage of the development of the standard or standardisation deliverables;
   (c) the expected date for their adoption;
   (d) the Union legislation or policies which the standard or standardisation deliverable supports, where relevant;
   (e) the references of any international standards on which the standard or standardisation deliverable is based, where relevant.
3. Each European standardisation organisation and each national standardisation body shall make its work programme available on its website or any other publicly available website.
4. Each European standardisation organisation and national standardisation body shall, without delay, notify the other European standardisation organisations, the national standardisation bodies and the Commission of the publication of its work programme.

5. National standardisation bodies shall not object to a subject for standardisation in their work programme being considered at European level by the European standardisation organisations and shall not undertake any action which could prejudice a decision in that regard.

6. During the development of the requested standards and standardisation deliverables, national standardisation bodies shall not take any action which could prejudice the intended harmonisation and, in particular, shall not publish new, revised or amended national standards or standardisation deliverables in the field in question.

Article 16

Transparency of development of standards by European standardisation organisations and national standardisation bodies

1. Each European standardisation organisation and national standardisation body shall send, in electronic form, any draft requested standards and standardisation deliverables, European standards, European standardisation deliverables and national standards to other European standardisation organisations, national standardisation bodies or the Commission, upon their request.

2. Each European standardisation organisation and national standardisation body shall take due account of any comments received from other European standardisation organisations, national standardisation bodies or the Commission with respect to drafts referred to in paragraph 1 and reply to those comments within three months from the date of their receipt.

3. When a national standardisation body receives comments indicating that the draft standard or standardisation deliverable would have a negative impact on the internal market, it shall consult the European standardisation organisations and the Commission before it decides whether to adopt it.

4. National standardisation bodies shall:

   (a) ensure access to draft national standards in such a way that all relevant parties in particular those established in other Member States have the opportunity to submit their comments;

   (b) allow other national standardisation bodies to send an observer in the planned activities.

5. After the Commission has published the reference of a requested standard in accordance with Article 25 or Article 31, national standardisation bodies shall withdraw all national standards that conflict with the referenced standard within a reasonable timeframe and shall not publish any new national standards which are not in line with the referenced standard.

SECTION 2
INCLUSIVENESS AND STAKEHOLDER PARTICIPATION

Article 17

Stakeholder participation in European standardisation

1. The European standardisation organisations shall enable the appropriate representation and effective participation of all relevant stakeholders, including

SMEs, consumer organisations, environmental and social stakeholders, research and innovation stakeholders as well as public authorities, in their standardisation activities.

2. The European standardisation organisations shall encourage and facilitate the appropriate representation at technical level of undertakings, research and innovation stakeholders, including open-source organisations, and shall promote their awareness as regards standardisation processes.

3. The European standardisation organisations shall collaborate with public authorities, in particular with market surveillance authorities in Member States.

Article 18

European stakeholder organisations

1. The Commission shall designate as European stakeholder organisations one European organisation representing SMEs, one European organisation representing consumers, one European organisation representing environmental interests and one European organisation representing social interests. The Commission shall designate European stakeholder organisations which meet the criteria set out in Annex II by means of implementing acts following an open, non-discriminatory and transparent process. The designation shall take place at least every four years.

2. The European stakeholder organisations designated in accordance with paragraph 1 shall participate in the standardisation activities of the European standardisation organisations and of the designated standards development organisations in support of Union legislation and policies relevant to the interests they represent to ensure that those interests are duly taken into account in the development of requested standards and standardisation deliverables.

3. The European standardisation organisations shall facilitate the effective representation and participation of European stakeholder organisations in all of the following stages of the development of requested standards or standardisation deliverables relevant to the interests they represent:

   (a) the proposal and acceptance of new work items;

   (b) technical discussions on proposals;

   (c) the submission of comments on drafts standards and standardisation deliverables;

   (d) the revision and amendment of existing referenced standards and standardisation deliverables.

4. The European stakeholder organisations shall ensure the dissemination of information and awareness-building towards the stakeholders they represent on the development, adoption, revision and amendment of requested standards and standardisation deliverables, relevant to the interests they represent.

5. The European stakeholder organisations shall send an annual report on their activities to the Commission by 31 January each year. This report shall contain detailed information about the membership of such organisations and the activities undertaken by them pursuant to paragraphs 2, 3 and 4.

Article 19

Participation of the Commission's research facilities and Union agencies in European standardisation

1. The Commission's research facilities and relevant Union agencies may provide the European standardisation organisations with scientific and technical input in their areas of expertise, to ensure that European standards and European standardisation deliverables promote innovation uptake and valorisation of European research and innovation results.

2. The European standardisation organisations shall facilitate cooperation with the Commission's research facilities and with relevant Union agencies in the development of European standards and European standardisation deliverables, including by allowing free participation in their technical bodies and providing them with free access to such standards and standardisation deliverables, as well as to preparatory and explanatory documents.

Article 20

Stakeholder participation in national standardisation

1. National standardisation bodies shall enable effective participation of all relevant stakeholders, including SMEs, consumer organisations, environmental and social stakeholders, research and innovation stakeholders, as well as public authorities in their standardisation activities.

2. National standardisation bodies shall ensure for SMEs, consumer organisations, environmental and social stakeholders, research and innovation stakeholders as well as public authorities all of the following:

   (a) identifying, in their annual work programmes, the standardisation projects, which are of particular interests to those stakeholders;

   (b) granting access to standardisation activities, without obliging them to become members of a national standardisation body;

   (c) granting free access to participate in their standardisation activities, or allow for such participation under reduced rates;

   (d) granting free access to draft standards and standardisation deliverables;

   (e) applying reduced rates for the provision of standards and standardisation deliverables and for other services provided by national standardisation bodies to facilitate the use of standards and standardisation deliverables.

Article 21

Participation of national public authorities in European standardisation

Member States shall, where appropriate, encourage the participation of public authorities, including market surveillance authorities, in national standardisation activities aimed at the development, revision or amendment of requested standards and standardisation deliverables.

SECTION 3
STANDARDISATION REQUESTS TO EUROPEAN STANDARDISATION ORGANISATIONS

Article 22

Consultation of European standardisation organisations

1. Where the Commission services have identified the need for a standard or standardisation deliverable, they shall first consult, by any appropriate means, the European standardisation organisations on their ability to accept a standardisation request on the standardisation need and to develop quality standards or standardisation deliverables on time.

2. The consultation referred to in paragraph 1 may cover:

   (a) the existence and maturity of relevant international, European or national standardisation processes;

   (b) the capacity and preparedness of the European standardisation organisations to deliver the standard or standardisation deliverable within a set timeframe;

   (c) the expected duration of the standardisation process;

   (d) the expected stakeholder participation and inclusiveness of the standardisation process;

   (e) the relevance, quality and market uptake of existing technical specifications or standards;

   (f) the expected availability of the technical expertise and resources necessary for the development of the standard or standardisation deliverable and the possibility to restrict participation during the development process of such standards or standardisation deliverables;

   (g) any other information that the Commission may find relevant to assess the ability of European standardisation organisations to develop quality standard or standardisation deliverable to address the standardisation need.

3. The relevant European standardisation organisations shall reply within one month of receipt of the consultation.

4. The Commission shall assess the response referred to in paragraph 3 of this Article, or lack thereof, and based on that assessment, may:

   (a) issue a standardisation request to one or more European standardisation organisations in accordance with Article 23;

   (b) issue a standardisation request to one or more designated standards development organisations in accordance with Article 29;

   (c) adopt common specifications in accordance with Article 32.

Article 23

Standardisation requests to European standardisation organisations

1. The Commission may address a standardisation request to one or more European standardisation organisations to develop, revise or amend European standards or

European standardisation deliverables to be referenced in the *Official Journal of the European Union*. The Commission shall adopt the standardisation request by means of implementing acts.

2. The standardisation request shall contain all of the following:

   (a) the requirements regarding the content to be met by the requested standards or standardisation deliverables;

   (b) a deadline for the delivery of each requested standard or standardisation deliverable;

   (c) a date of expiry.

3. The standardisation request may:

   (a) specify the intended legal effect of the requested standards or standardisation deliverables;

   (b) specify the steps to be taken for the timely delivery of the requested standards or standardisation deliverables;

   (c) specify requirements for the cooperation between the European standardisation organisations to which the standardisation request is addressed;

   (d) specify requirements for the participation of targeted stakeholders in the standardisation process;

   (e) require the European standardisation organisations to take into account identified existing technical specifications or standards;

   (f) specify requirements for periodic revisions of the requested standards or standardisation deliverables;

   (g) require the delivery of harmonised standardisation deliverables as a step towards harmonised standards;

   (h) restrict participation in the standardisation process of requested standards or standardisation deliverables related to Union strategic assets, interests, autonomy or security to representatives of legal entities which are established in Member States and have their executive management structures in the Union, and are not subject to control by a third country or a legal entity established in a third country, or to entities established in third countries that effectively meet the interests of the Union;

   (i) set specific requirement for the cooperation between European standardisation organisations and international standardisation bodies, including requirements related to the exception referred to in Article 35(2);

   (j) specify any other requirements which the Commission may find necessary for the development of the requested standards and standardisation deliverables.

4. Before adopting a standardisation request, the Commission shall publish the draft standardisation request on the EU Standards Platform, except in justified cases or where it intends to amend a standardisation request as regards the deadlines for the delivery of requested standards or standardisation deliverables, the expiry date set out in the standardisation request, or the clarification of the requirements to be met. The European standardisation organisations, the European stakeholder organisations and European sectoral experts may provide their opinions on the request within one month following the publication of the draft standardisation request.

5. The Commission shall endeavour to adopt the implementing act referred to in paragraph 1 within 12 months from the date of receipt of the response to the consultation referred to in Article 22(3) and within three months from the end of the consultation referred to in paragraph 4 of this Article.

6. By way of derogation to paragraph 5 of this Article, where the standardisation request specifies requirements referred to in paragraph 3, points (g) to (i), of this Article, the Commission shall adopt the implementing act referred to in paragraph 1 of this Article in accordance with the examination procedure referred to in Article 40(3). The Commission shall endeavour to submit the draft implementing act to the vote of the committee referred to in Article 40(1) within 12 months from the date of receipt of the response to the consultation referred to in Article 22(4) and within six months from the end of the consultation referred to in paragraph 4 of this Article.

7. The relevant European standardisation organisations shall indicate whether they accept the standardisation request within one month from the date of its notification. The Commission shall make available the adopted standardisation request on the EU Standards Platform and indicate on that Platform whether and which European standardisation organisations have accepted it.

Article 24

Implementation of standardisation requests addressed to European standardisation organisations

1. Where one or more European standardisation organisations have accepted a standardisation request, they shall regularly report to the Commission on the activities they have undertaken and the progress they have achieved in developing the requested standards and standardisation deliverables to deliver them within the deadlines set out in the standardisation request.

2. The European standardisation organisations shall provide the Commission with all draft documents circulated for public comments or scrutiny, and relevant normative references, and upon request any documents drafted in response to a standardisation request. The Commission may provide its comments on the draft requested standards and standardisation deliverables. The European standardisation organisations shall take due account of the Commission's comments on those draft documents to promote compliance in view of the assessment by the Commission referred to in Article 25(2).

Article 25

Assessment of requested standards and standardisation deliverables delivered by European standardisation organisations

1. The European standardisation organisations shall deliver the requested standards or standardisation deliverables to the Commission as soon as they are adopted and by the deadline for their delivery set out in the standardisation request.

2. The Commission shall assess, with the support of the European standardisation organisations, within six months of their delivery, the compliance of the delivered standards or standardisation deliverables with the standardisation request and with the requirements set out in the relevant Union legislation, or, where appropriate, with the objectives of the relevant Union policies.

3. Where a requested standard or standardisation deliverable appropriately complies with the standardisation request and satisfies the requirements, set out in the relevant Union legislation, which it aims to cover, or, where appropriate, the objectives of the relevant Union policies, the Commission shall publish its reference in the *Official Journal of the European Union* either by means of implementing acts under this Regulation or by other means as provided for in the relevant Union legislation. The Commission shall endeavour to publish the reference of such a standard or standardisation deliverable within three months from the date of the positive outcome of the assessment referred to in paragraph 2.

4. Where a requested standard or standardisation deliverable appropriately complies with the standardisation request and partially satisfies the requirements, set out in the relevant Union legislation, which it aims to cover, the Commission may publish its reference with restrictions in the *Official Journal of the European Union* either by means of implementing acts under this Regulation or by other means as provided for in the relevant Union legislation.

5. Where a requested standard or standardisation deliverable does not satisfy the requirements, set out in the relevant Union legislation, which it aims to cover, or, where appropriate, the objectives of the relevant Union policies, or does not appropriately comply with the standardisation request, the Commission shall inform the European standardisation organisations within six months from the date of the delivery of that standard or standardisation deliverable, except in duly justified cases.

6. The European standardisation organisations shall notify the Commission without delay when they engage in the process of revising or amending a referenced standard or standardisation deliverable. Where the standardisation request has not expired at the moment of delivery of the revised or amended standard or standardisation deliverable, the Commission shall publish the reference to that standard or standardisation deliverable in the *Official Journal of the European Union* either by means of implementing acts under this Regulation, or by other means as provided for in the relevant Union legislation. In this regard, it shall publish the reference without the need to adopt a new standardisation request or amend the corresponding standardisation request, if the changes to the referenced standard or standardisation deliverable appropriately comply with the standardisation request and satisfy the requirements, set out in the relevant Union legislation, which it aims to cover or, where appropriate, the objectives of the relevant Union policies.

7. Where a reference of a harmonised standard has been published in the *Official Journal of the European Union* in accordance with paragraph 3, the reference of the corresponding harmonised standardisation deliverable shall be withdrawn.

8. Where the requested standards or standardisation deliverables have not been delivered within the deadline set out in the standardisation request, the Commission has deemed them to be non-compliant in accordance with paragraph 5 of this Article, or it has deemed the steps referred to in Article 23(3), point (b), not to have been appropriately taken, it may take any of the following decisions:

   (a) amend the standardisation request to the European standardisation organisation;

   (b) repeal the standardisation request to the European standardisation organisation and issue a standardisation request to one or more standards development organisations in accordance with Article 29;

(c) adopt common specifications in accordance with Article 32.

Chapter 4
Other standardisation processes and safeguard mechanisms

SECTION 1
STANDARDISATION REQUESTS TO DESIGNATED STANDARDS DEVELOPMENT ORGANISATIONS

Article 26

Designation of standards development organisations

1. The Commission may, by means of implementing acts adopted in accordance with the examination procedure referred to in Article 40(3), designate a standards development organisation which may be requested to develop, revise or amend standards and standardisation deliverables in accordance with Article 29.

2. The Commission may only designate, in accordance with paragraph 1 of this Article, a standards development organisation which is able to ensure that its processes for the development of standards and standardisation deliverables meet the requirements set out in Article 27.

3. The Commission may, by means of implementing acts adopted in accordance with the examination procedure referred to in Article 40(3), withdraw the designation referred to in paragraph 1 of this Article where the standards development organisation no longer complies with the requirements laid down in Article 27 or is otherwise no longer able to effectively serve the interests of the Union.

4. The Commission shall publish the list of designated standards development organisations on the EU Standards Platform.

Article 27

Requirements for the designated standards development organisations

1. Standards development organisations designated in accordance with Article 26 shall meet all of the following requirements:

   (a) not be an international standardisation body, a national standardisation body or a standardisation body of a third country that is a member of international standardisation bodies;

   (b) comply with the principles of openness, transparency, neutrality and consensus as set out in paragraph 2 of this Article;

   (c) ensure that their processes for the development of requested standards and standardisation deliverables meet the requirements set out in paragraph 3 of this Article.

2. The designated standards development organisations shall ensure all of the following:

   (a) that standards and standardisation deliverables are developed on the basis of open decision-making procedures that are accessible to all interested parties in

the markets that are concerned by such standards and standardisation deliverables;

(b) that their decision-making process is collaborative and consensus based and does not favour any particular stakeholder;

(c) that their work programmes are transparent.

3. When developing standards and standardisation deliverables requested in accordance with Article 29, designated standards development organisations shall ensure all of the following:

(a) that their processes are inclusive, by enabling the effective participation of all relevant stakeholders, in particular Union stakeholders and the European stakeholder organisations referred to in Article 18;

(b) that they take due account of Union interests, insofar as those interests are represented;

(c) that they comply with the requirements set out in this Regulation.

Article 28

Transparency of development of requested standards and standardisation deliverables by designated standards development organisations

1. Each designated standards development organisation shall send in electronic form any draft requested standards or standardisation deliverables to European standardisation organisations upon their request. European standardisation organisations may send their comments as regards the coherence of the draft requested standards and standardisation deliverables with their referenced standards and standardisation deliverables to designated standards development organisations within one month from the date of receipt of the draft requested standards or standardisation deliverables.

2. Each designated standards development organisation shall take due account of any comments received from European standardisation organisations with respect to drafts referred to in paragraph 1 and reply to those comments within three months from the date of their receipt.

Article 29

Standardisation requests to designated standards development organisations

1. The Commission may address, by means of implementing acts, a standardisation request to one or more designated standards development organisations to develop, revise or amend standards or standardisation deliverables to be referenced in the *Official Journal of the European Union*, in any of the following cases:

(a) the European standardisation organisations consulted in accordance with Article 22 have not replied or have informed the Commission that they do not intend to accept the standardisation request regarding the standards or standardisation deliverables;

(b) the Commission deems that, following a consultation under Article 22, the response given to the points referred to in paragraph 2 of that Article would not

lead to the timely and quality delivery of the requested standards or standardisation deliverables;

(c) none of the European standardisation organisations to which the Commission addressed a request in accordance with Article 23 have accepted it;

(d) the requested standards or standardisation deliverables have not been delivered within the deadline set out in the standardisation request issued in accordance with Article 23;

(e) the Commission deems that the steps referred to in Article 23(3), point (b), have not been appropriately taken;

(f) the Commission deems that the requested standards or standardisation deliverables are non-compliant in accordance with Article 25(5).

2. The standardisation request shall contain all of the following:

(a) the requirements regarding the content to be met by the requested standards or standardisation deliverables

(b) a deadline for their delivery;

(c) a set date of expiry.

3. The standardisation request may:

(a) specify the intended legal effect of the requested standards or standardisation deliverables;

(b) specify the steps to be taken for the timely delivery of the requested standards or standardisation deliverables;

(c) specify requirements for the cooperation between the designated standards development organisations to which the standardisation request is addressed;

(d) specify requirements for the participation of targeted stakeholders in the standardisation process;

(e) require the designated standards development organisations to take into account identified existing technical specifications or standards;

(f) specify requirements for periodic revisions of the requested standards or standardisation deliverables;

(g) restrict participation in the standardisation process of requested standards or standardisation deliverables related to Union strategic assets, interests, autonomy or security to representatives of legal entities which are established in Member States and have their executive management structures in the Union, and are not subject to control by a third country or a legal entity established in a third country, or to entities in third countries that effectively meet the interests of the Union;

(h) set specific requirements for the cooperation between designated standards development organisations and international standardisation bodies, including requirements related to the exception referred to in Article 35(2);

(i) specify any other requirements which the Commission may find necessary for the development of the requested standards and standardisation deliverables.

4. Before adopting a standardisation request, the Commission shall publish the draft standardisation request on the EU Standards Platform, except in justified cases or where it intends to amend a standardisation request as regards the deadlines for the delivery of requested standards or standardisation deliverables, the expiry date set out in the standardisation request, or the clarification of the requirements to be met. The designated standards development organisations, the European stakeholder organisations, European standardisation organisations and European sectoral experts may provide their opinions within one month following the publication of the draft standardisation request.

5. The Commission shall adopt the implementing act referred to in paragraph 1 of this Article in accordance with the examination procedure referred to in Article 40(3). The Commission shall endeavour to submit the draft implementing act to the vote of the committee referred to in Article 40(1) within six months from the end of the consultation referred to in paragraph 4 of this Article.

6. The relevant designated standards development organisations shall indicate whether they accept the standardisation request within one month from the date of its notification. The Commission shall make available the adopted standardisation requests on the EU Standards Platform and indicate on that Platform whether and which designated standards development organisations have accepted it.

Article 30

Implementation of standardisation requests addressed to designated standards development organisations

1. Where one or more designated standards development organisations have accepted a standardisation request, they shall regularly report to the Commission on the activities they have undertaken and the progress they have achieved in developing the requested standards and standardisation deliverables to deliver them within the deadlines set out in the standardisation request.

2. The designated standards development organisations shall provide the Commission with all draft documents circulated for public comments or scrutiny, and relevant normative references, and upon request any documents drafted in response to a standardisation request. The Commission may provide its comments on the draft requested standards and standardisation deliverables. The designated standards development organisations shall take due account of the Commission's comments on those draft documents to promote compliance in view of the assessment by the Commission referred to in Article 31(2).

Article 31

Assessment of requested standards and standardisation deliverables delivered by designated standards development organisations

1. The designated standards development organisations shall deliver the requested standards or standardisation deliverables to the Commission as soon as they are adopted and by the deadline for their delivery set out in the standardisation request.

2. The Commission shall assess, with the support of the relevant designated standards development organisations and the relevant sectoral expert groups, within six months of their delivery, the compliance of the delivered standards or standardisation

deliverables with the standardisation request and with the requirements set out in the relevant Union legislation, or, where appropriate, with the objectives of the relevant Union policies, and the coherence of the delivered standards or standardisation deliverables with other relevant referenced standards or standardisation deliverables.

3. Where a requested standard or standardisation deliverable appropriately complies with the standardisation request, satisfies the requirements, set out in the relevant Union legislation, which it aims to cover, or, where appropriate the objectives of the relevant Union policies, and is coherent with other relevant referenced standards and standardisation deliverables, the Commission shall publish its reference in the *Official Journal of the European Union* either by means of implementing acts under this Regulation or by other means as provided for in the relevant Union legislation. The Commission shall endeavour to publish the reference of such a standard or standardisation deliverable within three months from the date of the positive outcome of the assessment referred to in paragraph 2.

4. Where a requested standard or standardisation deliverable partially satisfies the requirements, set out in the relevant Union legislation, which it aims to cover, the Commission may publish its reference with restrictions in the *Official Journal of the European Union* either by means of implementing acts under this Regulation or by other means as provided for in the relevant Union legislation.

5. Where a requested standard or standardisation deliverable does not satisfy the requirements, set out in the relevant Union legislation, which it aims to cover, or, where appropriate, with the objectives of the relevant Union policies, does not appropriately comply with the standardisation request, or is not coherent with other relevant referenced standards and standardisation deliverables, the Commission shall inform the relevant designated standards development organisations within six months from the date of the delivery of that standard or standardisation deliverable, except in duly justified cases.

6. The designated standards development organisations shall notify the Commission without delay when they engage in the process of revising or amending a referenced standard or standardisation deliverable. Where the standardisation request has not expired at the moment of adoption of the revised or amended standard or standardisation deliverable, the Commission shall publish the reference to that standard or standardisation deliverable in the *Official Journal of the European Union* either by means of implementing acts under this Regulation or by other means as provided for in the relevant Union legislation. In this regard, it shall publish the reference without the need to adopt a new standardisation request or amend the corresponding standardisation request, if the changes to the referenced standard or standardisation deliverable appropriately comply with the standardisation request, satisfy the requirements, set out in the relevant Union legislation, which it aims to cover, or, where appropriate, the objectives of the relevant Union policies, and are coherent with other relevant referenced standards and standardisation deliverables.

7. Where the requested standards or standardisation deliverables have not been delivered within the deadline set out in the standardisation request, the Commission has deemed them to be non-compliant in accordance with paragraph 5 of this Article, or the Commission has deemed the steps referred to in Article 29(3), point (b), not to have been appropriately taken, it may take any of the following decisions:

   (a) repeal or amend the standardisation request to the relevant designated standards development organisation;

(b) adopt common specifications in accordance with Article 32.

SECTION 2
COMMON SPECIFICATIONS AND SAFEGUARD MECHANISMS

Article 32

Common specifications

1. The Commission may adopt implementing acts establishing common specifications that provide presumption of conformity with the requirements set out in the relevant Union legislation.

2. The Commission may adopt the implementing act referred to in paragraph 1 of this Article where:

   (a) the European standardisation organisations consulted in accordance with Article 22 have not replied or have informed the Commission that they do not intend to accept the standardisation request regarding the standards or standardisation deliverables;

   (b) the Commission deems that, following the consultation under Article 22, the response given to the points referred to in paragraph 2 of that Article would not lead to the timely and quality delivery of the requested standards or standardisation deliverables; or

   (c) the Commission has withdrawn the reference to a harmonised standard in accordance with Article 33.

3. The Commission may adopt the implementing act referred to in paragraph 1 of this Article, where it has adopted a standardisation request covering the requirements referred to in paragraph 1 of this Article in accordance with Article 23 or 29, where there is no harmonised standard covering the requirements referred to in paragraph 1 of this Article and no such harmonised standard is expected to be referenced within a reasonable period, and where any of the following conditions is met:

   (a) none of the European standardisation organisations or designated standards development organisations to which the Commission addressed a request in accordance with Article 23 or 29 respectively has accepted it;

   (b) the requested standard or standardisation deliverable has not been delivered within the deadline set out in the standardisation request;

   (c) the Commission deems that the steps referred to in Article 23(4), point (b), or 29(3), point (b), have not been appropriately taken;

   (d) the Commission deems that the requested standard or standardisation deliverable is non-compliant in accordance with Article 25(5) or 31(5).

4. The Commission shall adopt the implementing act referred to in paragraph 1 of this Article in accordance with the examination procedure referred to in Article 5 of Regulation (EU) 182/2011. For that purpose, the competent committee shall be the committee referred to in the corresponding Union legislation or, in the absence of such a committee, the committee referred to in Article 40 in accordance with the procedure referred to in Article 40(3).

5. Before preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 40 that it considers that the conditions referred to in paragraph 2 or 3 of this Article are fulfilled.

6. When preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall take into account the views of the relevant expert groups and shall duly consult all relevant stakeholders. The Commission may use, where relevant, the documents referred to in Article 24(2) or 30(2) as a basis for the implementing act.

7. Where the Commission adopts an implementing act referred to in paragraph 1, it shall make it available on the EU Standards Platform.

8. Where a standard is adopted following the standardisation request referred to in paragraph 3 and where a reference to that standard is published in the *Official Journal of the European Union*, the Commission shall repeal or amend the implementing act referred to in paragraph 1, or the parts thereof, which cover the same requirements as those covered by that standard.

Article 33

Safeguard notification of referenced standards and standardisation deliverables and common specifications

1. Where a Member State, the European Parliament or the Commission considers that a referenced standard or standardisation deliverable, or parts thereof, or common specification, or parts thereof, do not satisfy the requirements, set out in the relevant Union legislation, which they aim to cover, it shall immediately notify the other Member States, the European Parliament, and the Commission, where applicable, and include a detailed explanation to them.

2. If a Member State, the European Parliament or the Commission has not objected to the notification referred to in paragraph 1 within one month following its receipt, the Commission shall decide within six months from the notification referred to in paragraph 1 whether to maintain with restrictions or withdraw the reference to that standard or standardisation deliverable from the *Official Journal of the European Union* either by means of implementing acts under this Regulation, or by other means as provided for in the relevant Union legislation, or to amend or repeal the common specification.

3. If a Member State, the European Parliament or the Commission has objected to the notification within one month following its receipt, the Commission shall consult the notifier and the objecting parties, assess the information received and decide within 12 months from the notification referred to in paragraph 1, whether to maintain, to maintain with restrictions or to withdraw the reference to that standard or standardisation deliverable from the *Official Journal of the European Union* either by means of implementing acts under this Regulation, or by other means as provided for in the relevant Union legislation, or to maintain, amend or repeal the common specification.

Article 34

Withdrawal of referenced standards or standardisation deliverables

The European standardisation organisations and designated standards development organisations shall notify the Commission when they engage in the process of withdrawing a referenced standard or standardisation deliverable. The Commission may withdraw the reference of such a standard or standardisation deliverable from the *Official Journal of the European Union* either by means of implementing acts under this Regulation or by other means as provided for in the relevant Union legislation.

Chapter 5
Measures to improve Union coordination in international standardisation

Article 35

International first principle and cooperation with international standardisation bodies

1. Where international standards exist or their completion is imminent, European standardisation organisations and designated standards development organisations shall use them, or the relevant parts thereof, as a basis for the requested standards and standardisation deliverables that they develop.

2. If the Commission considers that an existing or draft international standard, or relevant parts thereof, is ineffective or inappropriate for the legitimate objective pursued, it may specify in the standardisation request in accordance with Article 23(3), point (i), or 29(3), point (h), that European standardisation organisations or designated standards development organisations shall not use an existing or draft international standard, or the relevant parts thereof, as a basis for the requested standards and standardisation deliverables.

Article 36

European coordination on international standardisation

1. The Commission, in cooperation with European standardisation organisations, shall facilitate the exchange of information with and between Member States as regards international standardisation and shall promote the participation of European experts in international standardisation.

2. Member States and European standardisation organisations shall regularly inform the Commission of relevant developments in their international standardisation activities.

Article 37

Cooperation with other standards development organisations

1. European standardisation organisations and designated standards development organisations shall inform and consult the Commission before they enter into an agreement with a standards development organisation which affect their standardisation activities undertaken in support of Union legislation and policies. They shall notify the Commission without delay of any amendment, renewal, suspension or termination of such agreements.

2. European standardisation organisations and designated standards development organisations shall promote requested standards and standardisation deliverables when they participate in the work of other standards development organisations.

Chapter 6
Governance, delegated powers and committee procedures

Article 38

Centre of Excellence on European Standardisation

1. The Centre of Excellence on European Standardisation within the Commission shall have the following tasks:

   (a) coordinate the implementation of this Regulation by the Commission;

   (b) promote the cooperation between the Commission and European standardisation organisations;

   (c) foster the performance of the European standardisation system, including the contribution of European stakeholder organisations;

   (d) identify standards development organisations active in areas identified in the annual Union work programme on European standardisation, monitor their activities and assess whether they meet the requirements set out in Article 27;

   (e) coordinate the participation of sectoral experts from the Commission, the relevant Union agencies and the Member States in standardisation activities related to Union legislation and policies;

   (f) improve coordination across European standardisation actors in international standardisation activities;

   (g) promote the integration of the Union's research and innovation policies with standardisation activities, and the development of education and skills on standardisation within the Union;

   (h) coordinate the development of pre-normative specifications in areas of public relevance and support the elaboration of common specifications.

Article 39

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 10(2) is conferred on the Commission for an indeterminate period of time from [*OP: insert date of entry into force of this Regulation*].

3. The delegation of power referred to in Article 10(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. Delegated acts adopted pursuant to Article 10(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of those acts to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 40

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 41

Evaluation and review

1. By [*OP: insert date of entry into force of this Regulation + five years*] and every five years thereafter, the Commission shall present a report to the European Parliament and to the Council on the implementation of this Regulation.

2. By [*OP: insert date of application of this Regulation + five years*], the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council.

Chapter 7
Final provisions

Article 42

Repeal

1. Regulation (EU) No 1025/2012 is repealed. References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III to this Regulation

2. Article 48 of Regulation (EU) of 2023/988 of the European Parliament and of the Council is repealed.

Article 43

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*OP: insert date of entry into force + six months*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation on European standardisation of the European Parliament and of the Council, repealing Regulation (EU) No 1025/2012 of the European Parliament and of the Council

1.2. Policy area(s) concerned

Standards policy, Single Market, Industrial Policy

1.3. Objective(s)

1.3.1. General objective(s)

The general objectives pursued by this legislative proposal are:

(a) Fostering global EU competitiveness and technological sovereignty, by making the European standardisation system faster, more agile, more inclusive and better coordinated, so that it supports the timely delivery of standards in strategic areas and reinforces the EU's role in international standard-setting;

(b) Ensuring the better functioning of the EU Single Market, by increasing the timely availability of harmonised standards and other standards in support of Union legislation and policies, thereby reducing divergent national approaches and facilitating the circulation of compliant products and services across the Union;

(c) Reducing regulatory costs for EU businesses, in particular SMEs, by improving the accessibility, clarity and usability of harmonised standards, thereby simplifying conformity assessment and reducing legal uncertainty.

1.3.2. Specific objective(s)

Specific objective No 1

Improving the responsiveness of the European standardisation system: to accelerate the development and delivery of harmonised standards and other standards in support of Union legislation and policies by making the system more agile, reducing delays, and ensuring standards are timely, high-quality and aligned with the state of the art.

Specific objective No 2

Ensuring a financially viable and inclusive European standardisation system: to maintain a well-functioning and inclusive European standardisation system by increasing participation from SMEs, civil society and industry experts while ensuring financial sustainability and providing free access to harmonised standards and standards in support of Union legislation and policies.

Specific objective No 3

Consolidating the EU's influence in international standardisation: to strengthen the EU's role in global standard-setting by improving coordination among EU actors and reinforcing strategic autonomy in key sectors.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal is expected to improve the responsiveness, sustainability and international influence of the European standardisation system, with positive effects for the main beneficiary groups, in particular market operators and SMEs.

EU businesses would benefit from faster and more predictable delivery of standards supporting Union legislation and policy priorities, reducing market fragmentation and facilitating compliance. SMEs should benefit in particular from greater transparency, stronger stakeholder participation and better access to standardisation processes, although their capacity constraints may still limit effective engagement without targeted support. A more coherent and timely standardisation system would help firms bring innovative products and services to the Single Market more rapidly, strengthen legal certainty and reduce costs linked to divergent national approaches.

Consumers are expected to benefit indirectly from standards that better reflect public policy objectives, notably in safety, accessibility, sustainability and digital trust. This should reinforce confidence in products and services placed on the Union market and support a higher level of consumer protection.

European standardisation organisations and national standardisation bodies would face some adaptation needs, including adjustments to governance, planning and cooperation practices. At the same time, they would benefit from clearer priorities, reinforced coordination and a more effective framework for delivering standards in support of Union legislation and policy objectives.

Overall, the proposal is expected to generate net benefits for targeted groups, while requiring limited but necessary organisational adjustment within the European Standardisation System.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

The improved monitoring of the implementation of the Standardisation Regulation by the Commission is a key dimension of this initiative.

Specific objective No 1

The monitoring of the responsiveness of the European standardisation system will be conducted through the monitoring of the average time for referencing a harmonised standard or a standard in support of Union legislation and policies, from the identification of the standardisation need to the referencing in the Official Journal of the European Union. The duration of the standardisation process will be assessed at each step (adoption of the standardisation request, development of the standard and referencing of the standard). The current benchmark is 6.1 years, and the target is to reduce the average time needed to reference a standard to 4.0 years on average. The responsiveness will also be monitored by the quality of delivered standards in support of Union legislation and policies, as measured by the number of delivered harmonised standards by European standardisation organisation or standards development organisations rejected by the Commission after their assessment. The current proportion is 32 % at publication stage and the target would be set at below 15 %.

Specific objective No 2

The monitoring of the sustainability of the European standardisation system will be conducted through the engagement of European standardisation organisations in delivering standards in support of Union legislation or policies, as measured by the

share of standardisation requests rejected by European standardisation organisations and by the share of pre-consultations of European standardisation organisations that lead to their refusal to engage in the requests. This will be complemented by an assessment of the level of participation of experts in the standardisation process, inferred from the total number of experts engaged in EU standardisation activities, including SME, civil society and R&I experts, as available in the transparency register set up by European standardisation organisations.

Specific objective No 3

The EU influence on international standardisation will be monitored primarily through the EU influence in international organisations ISO and IEC, measured by the number of technical committees chaired by an EU representative, identifying specifically technical committees active in strategic technologies.

1.4. The proposal/initiative relates to:

☑ a new action

☐ a new action following a pilot project / preparatory action[1]

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The initiative responds to the need to address the structural shortcomings of the current European standardisation system by improving its responsiveness, ensuring more timely and reliable delivery of harmonised standards, improving access and inclusiveness, safeguarding the sustainability of the system, and strengthening the Union's influence in international standardisation.

The initiative should contribute to a more harmonised, effective, efficient and coherent standardisation framework across the Single Market, supporting EU competitiveness, technological sovereignty, interoperability, legal certainty and the implementation of Union legislation and policies.

The initiative should enter into force in 2028 and could be complemented by targeted changes to relevant sectoral legislation to align them to the new framework for European standardisation.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at EU level (ex-ante):

Action at Union level is justified because the problems addressed by the initiative are structural, cross-border and inherent to the functioning of the European standardisation system and the Single Market. Harmonised standards apply across all Member States and the EEA and reduce barriers within the internal market by

[1] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

supporting interoperability, value-chain integration and consumer confidence; these outcomes cannot be secured through isolated national action. In the absence of EU action, the identified shortcomings would persist, and Member States could develop divergent national approaches outside the common framework, increasing fragmentation, barriers to entry and inequalities within the internal market.

Expected generated EU added value (ex-post):

The expected EU added value is a more harmonised, effective, efficient and coherent outcome across the internal market. The European standardisation system delivers added value through increased intra-EU and extra-EU trade, reduced compliance costs, greater inclusiveness and stronger EU influence in international standardisation compared with national systems. EU action is also expected to generate economies of scale for businesses and Member States and improve legal certainty and effectiveness through faster and higher-quality standards supporting Union legislation and policies.

1.5.3. Lessons learned from similar experiences in the past

Experience under the current Regulation shows that the European standardisation Regulation adopted in 2012 has produced improvements but remains insufficient to meet present needs. The targeted revision of the Regulation (EU) 2012/1025 implemented by Regulation (EU) 2022/2480 to reinforce the representation of national standardisation bodies of the EU in the decision-making process of European standardisation organisations has highlighted the relevance of introducing more oversight on the effective participation of national standardisation bodies in the standardisation process in support of Union legislation and policies. The Omnibus IV on digitalisation and common specifications has also confirmed the need for a horizontal and consistent approach to common specifications as fall back to harmonised standards when they are not available across Union legislation.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

The initiative will enter into force under the Multi-annual Financial Framework (MFF) for 2028-2034. The initiative is compatible with the Union's financial programming for the current MFF, and without prejudice to the outcome of negotiations on the next MFF, would be compatible with the future framework as proposed by the Commission. Funding opportunities to support the effective functioning of the internal market through standardisation processes may be available under the next MFF 2028-2034, including the future Single Market and Customs Programme, as well as the European Competitiveness Fund and the Horizon Europe 2028-2034 programme.

1.5.5. Assessment of the different available financing options, including scope for redeployment

Without prejudice to the outcome of negotiations on the next MFF, the appropriations foreseen from 2028 onwards are strictly indicative.

As regards financing options, new potential needs, notably to ensure the free and unrestricted access to standards in support of Union legislation and policies and the financial sustainability of the European standardisation system, in particular in the transition phase, may be covered through redeployment of resources used for standardisation activities, pending their continuation in the next MFF.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☑**unlimited duration**

– Implementation with a start-up period from 2028 to 2029,

– followed by full-scale operation.

The Regulation is expected to enter into force in 2028 and remains applicable for an unlimited duration, with a review after five years of implementation to assess the contribution of the Regulation to its objectives.

1.7. Method(s) of budget implementation planned[2]

☑**Direct management** by the Commission

– ☑by its departments, including by its staff in the Union delegations;

– ☑by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the

[2] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

The main budget implementation method is direct management by the Commission. Budget in support of the implementation of this Regulation can also be implemented under direct management by an Executive Agency.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The implementation of the Regulation will be primarily monitored through the performance framework introduced by the Regulation and the key performance indicators that the Commission will adopt pursuant to Article 11.

All information will be made available on the EU Standard platform created pursuant to Article 7 to allow the continuous monitoring of the contribution of the Regulation to its objectives. In addition, European standardisation organisations will report annually to the Commission on the implementation of the Regulation, as will European stakeholder organisations.

This Statement concerns staff expenditures and IT investments and operational costs. Standard rules for this type of expenditure apply.

No later than five years after the entry into force of the Regulation, the Commission will assess the contribution of this Regulation to the competitiveness of the Union, the functioning of the internal market, and to the simplification agenda through reduce compliance costs for businesses, including its contribution to the specific objectives specified in section 1.3.2.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The management mode for the initiative is direct management by the Commission. This is the most appropriate approach given the limited scope of Union expenditure incurred by the Regulation, which mostly consists of standard administrative and monitoring-related costs. Using established internal procedures ensures effective and efficient controls, low error rates, fast processing of transactions and minimal control costs.

The Regulation may also be implemented through direct management making use of potential funding opportunities under the next 2028-2034 Multiannual Financial Framework, including the upcoming Single Market and Customs Programme, while not pre-judging the outcome of the negotiations on the next Multiannual Financial Framework. Tasks may be implemented by the Commission or by the Executive Agency under delegation arrangements.

This approach builds on established structures and avoids creating new implementing bodies or parallel financial procedures. It is considered the most cost-effective option, as it allows funding to be closely linked to Union policy priorities, standardisation requests, agreed deliverables and performance indicators.

Payments will follow the modalities laid down in the relevant grant agreements and contracts, including pre-financing, interim payments where appropriate and payment of the balance following verification of the deliverables and eligible expenditure.

The control strategy will be based on the Commission’s internal control framework and the Financial Regulation. It will combine proportionate ex ante operational and financial checks, performance monitoring and risk-based ex post audits, with the aim of ensuring legality and regularity, timely contracting and payment, and reasonable control costs.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The initiative requires staff expenditure and IT investment and maintenance expenditures. Standard rules for this type of expenditure apply.

The main operational risk is insufficient administrative capacity to implement the activities stipulated in the Regulation, as well as risks concerning delays or non-delivery of standardisation work.

The financing of the operations of European standardisation organisations and European stakeholder organisation may create a risk of concentration of funding among a limited number of beneficiaries. These risks will be mitigated through clear eligibility and award criteria, defined deliverables, milestones and performance indicators in grant and contribution agreements, and regular reporting by beneficiaries. Implementation will be monitored against the agreed performance framework, allowing delays or underperformance to be identified at an early stage.

The internal control system will combine proportionate ex ante operational and financial checks, ongoing monitoring and risk-based ex post audits. Payments may be suspended, reduced or recovered where deliverables are not achieved or expenditure is not eligible, in accordance with the Financial Regulation.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The costs of controls will be estimated separately at Commission and Executive Agency level, based on their internal management and control systems and experience in implementing the standardisation strand of the Single Market and Customs Programme. As the Regulation will rely on existing funding mechanisms, procedures and beneficiaries, control costs are expected to remain proportionate to the value and risk profile of the funds managed.

Control intensity will be adapted to the type and value of each transaction and the risks identified. It will include checks on eligibility, procurement procedures, financial reporting, achievement of milestones and delivery of the agreed standardisation outputs, complemented by risk-based audits and recovery procedures.

The objective is to maintain the risk of error below 2 % at payment and at closure. Any errors detected after payment will be corrected through financial corrections, recoveries or reductions of subsequent payments.

2.3. Measures to prevent fraud and irregularities

The existing fraud-prevention measures applicable to the Commission and the Executive Agency will cover the expenditure under this Regulation. These include the Commission Anti-Fraud Strategy, the relevant service-level anti-fraud strategies, conflict-of-interest and exclusion checks, prevention of double funding, business-partner screening, risk-based monitoring and audits, and recovery procedures. Grant agreements and contracts will contain the standard anti-fraud, audit and access clauses. Suspected fraud or irregularities will be reported to OLAF and, where relevant, the EPPO. Appropriate ethics and anti-fraud guidance and training will also be provided to staff involved in managing the funds.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

The estimated impact on expenditure and staffing for 2028 and beyond is added for illustrative purposes only and does not pre-judge the next Multiannual Financial Framework. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the MFF 2028-2034 and thereafter shall be determined through the annual budgetary procedure. All appropriations and staffing allocations as of 2028 are indicative.

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[1]	from EFTA countries[2]	from candidate countries and potential candidates[3]	From other third countries	other assigned revenue
2	Internal market, implementation tools, market surveillance and European standardisation	Diff.	NO	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
//	//	//	//	//	//	//

1 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
2 EFTA: European Free Trade Association.
3 Candidate countries and, where applicable, potential candidates.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☑ The proposal/initiative requires the use of operational appropriations, as explained below

The proposal is estimated to require the use of operational appropriations that are commensurate to the current budget allocated to standardisation activities within the Single Market Programme.

The indicative estimate, while not pre-judging the next Multiannual Financial Framework, is EUR 177,575 million over the programming period 2028-2034 at current prices, based on the operational appropriations for standardisation within the Single Market Programme of EUR 23,714 million in 2027.

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	2

DG GROW			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
Operational appropriations										
Budget line Internal market, implementation tools, market surveillance and European standardisation	Commitments	(1a)	23,714	24,188	24,672	25,165	25,669	26,182	26,706	**176,297**
	Payments	(2a)	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	**p.m.**
Appropriations of an administrative nature financed from the envelope of specific programmes[1]										
Administrative support line of SMCP		(3)	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**

[1] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL appropriations for DG GROW	Commitments	=1a+1b +3	**23,714**	**24,401**	**24,885**	**25,378**	**25,882**	**26,395**	**26,919**	**177,575**
	Payments	=2a+2b +3	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**

			Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
TOTAL operational appropriations	Commitments	(4)	23,714	24,188	24,672	25,165	25,669	26,182	26,706	**176,297**
	Payments	(5)	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	**p.m.**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**
TOTAL appropriations under HEADING 2 of the multiannual financial framework	Commitments	=4+6	**23,714**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**177,575**
	Payments	=5+6	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**

			Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	23,714	24,401	24,885	25,378	25,882	26,395	26,919	**177,575**
	Payments	(5)	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	**p.m.**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**

TOTAL appropriations Under Heading 1 to 3	Commitments	=4+6	**23,714**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**177,575**
of the multiannual financial framework (Reference amount)	Payments	=5+6	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**

Heading of multiannual financial framework	4	‘Administrative expenditure’[2]							
DG GROW		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
• Human resources		2,890	3,181	3,181	3,181	3,181	3,181	3,181	**21,973**
• Other administrative expenditure		0	0	0	0	0	0	0	**0**
TOTAL DG GROW	Appropriations	**2,890**	**3,181**	**3,181**	**3,181**	**3,181**	**3,181**	**3,181**	**21,973**

Other DGs implementing standardisation requests		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
• Human resources		5,820	6,596	6,596	6,596	6,596	6,596	6,596	**45,396**
• Other administrative expenditure		0	0	0	0	0	0	0	**0**
TOTAL Other DGs	Appropriations	**5,820**	**6,596**	**6,596**	**6,596**	**6,596**	**6,596**	**6,596**	**45,396**

[2] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

TOTAL appropriations under HEADING 4 of the multiannual financial framework	(Total commitments = Total payments)	8,710	9,777	9,777	9,777	9,777	9,777	9,777	67,369

EUR million (to three decimal places)

		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
TOTAL appropriations under HEADINGS 1 to 4	Commitments	**32,424**	**34,182**	**34,670**	**35,168**	**35,676**	**36,194**	**36,722**	**245,036**
of the multiannual financial framework	Payments	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2028**		Year **2029**		Year **2030**		Year **2031**		Enter as many years as necessary to show the duration of the impact (see Section1.6)						**TOTAL**	
	OUTPUTS																	
	Type[3]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[4]…																		
- Output																		

[3] Outputs are products and services to be supplied (e.g. number of student exchanges financed, number of km of roads built, etc.).

[4] As described in Section 1.3.2. 'Specific objective(s)'

- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☑ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034
HEADING 4								
Human resources	8,710	9,777	9,777	9,777	9,777	9,777	9,777	**67,369**
Other administrative expenditure	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 4	**8,710**	**9,777**	**9,777**	**9,777**	**9,777**	**9,777**	**9,777**	**67,369**
Outside HEADING 4								
Human resources	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 4	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**
TOTAL	**8,710**	**9,990**	**9,990**	**9,990**	**9,990**	**9,990**	**9,990**	**68,647**

3.2.3.2. Total appropriations

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL 2028 - 2034**
HEADING 4								
Human resources	8,710	9,777	9,777	9,777	9,777	9,777	9,777	**67,369**
Other administrative expenditure	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 4	**8,710**	**9,777**	**9,777**	**9,777**	**9,777**	**9,777**	**9,777**	**67,369**

Outside HEADING 4								
Human resources	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 4	**0**	**0,213**	**0,213**	**0,213**	**0,213**	**0,213**	**0,213**	**1,278**
TOTAL	**8,710**	**9,990**	**9,990**	**9,990**	**9,990**	**9,990**	**9,990**	**68,647**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☑ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)[1]

VOTED APPROPRIATIONS	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**
• Establishment plan posts (officials and temporary staff)							
(Headquarters and Commission's Representation Offices)	43	48,5	48,5	48,5	48,5	48,5	48,5
(EU Delegations)	0	0	0	0	0	0	0
(Indirect research)	0	0	0	0	0	0	0
(Direct research)	0	0	0	0	0	0	0

[1] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

Other budget lines (specify)		0	0	0	0	0	0	0
• External staff (inFTEs)								
(AC, END from the 'global envelope')		3,5	3,5	3,5	3,5	3,5	3,5	3,5
(AC, AL, END and JPD in the EU Delegations)		0	0	0	0	0	0	0
Admin. Support line	• at Headquarters	0	0	0	0	0	0	0
[XX.01.YY.YY]	• in EU Delegations	0	0	0	0	0	0	0
(AC, END - Indirect research)		0	0	0	0	0	0	0
(AC, END - Direct research)		0	0	0	0	0	0	0
Other budget lines (specify) - Heading 4		0	0	0	0	0	0	0
Other budget lines (specify) - Outside Heading 4		0	0	0	0	0	0	0
TOTAL		**46,5**	**54**	**54**	**54**	**54**	**54**	**54**

The estimated impact on staffing for 2028 and beyond is added for illustrative purposes only and does not pre-judge the next Multiannual Financial Framework. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the Multiannual Financial Framework 2028-2034 and thereafter shall be determined through the annual budgetary procedure and the steering mechanism. All staffing allocations as of 2028 are indicative.

3.2.4.2. Total requirements of human resources

The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	**Exceptional additional staff**

		To be financed under Heading 4 or Research	To be financed from BA line	To be financed from fees
Establishment plan posts	48,5		N/A	
• External staff (CA, SNEs, INT)	3,5		2	

Description of tasks to be carried out by:

Officials and temporary staff	Task 1: Implementing the strategic planning and the increased accountability of the European Standardisation System: 0,5 FTE, hosted in the Centre. Task 2: Supporting the implementation of the flexibility to address requests to designated standards development organisations and the integration of specifications from other standards development organisations in standards and standardisation deliverables developed by European standardisation organisations: 3 FTE hosted in sectoral services responsible for implementing the standardisation requests. Task 3: Improving international coordination across EU standardisation actors: 1 FTE hosted in sectoral services responsible for implementing the standardisation requests. Task 4: Leading the Centre: 1 FTE, hosted in the Centre.
External staff	The set-up of the Expert Centre on European standardisation will improve coordination and oversight of the implementation of the Standardisation Regulation and will facilitate the implementation of the new tasks attributed to the Commission. The additional resources needs to implement the new Standardisation Regulation would be covered in majority by internal redeployments within the lead DG, DG GROW and within the services that use the Standardisation Regulation to support their legislation and policies. Nevertheless, despite the considerable efforts made by the Commission to redeploy its resources in the past year, some of the new tasks may need to be covered by an additional reinforcement of Commission staffing by 2 FTEs external staff to increase the Commission expertise and to ensure that further

	reallocation of existing human resources would not compromise the implementation of existing tasks. Task 2: Supporting the implementation of the flexibility to address requests to designated standards development organisations and the integration of specifications from other standards development organisations in standards and standardisation deliverables developed by European standardisation organisations: 1 FTE hosted in the Centre. Task 3: Improving international coordination across EU standardisation actors: 1 FTE, hosted in the Centre.

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 4 should be presented in the designated line.

The appropriations under Headings 1-3 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028 - 2034**
HEADING 4								
IT expenditure (corporate)	0	0	0	0	0	0	0	**0**
Subtotal HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Outside HEADING 4								

Policy IT expenditure on operational programmes	0	0	0	0	0	0	0	**0**
Subtotal outside HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
TOTAL	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☑ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

The current initiative is fully compatible with the current multi-annual financial framework and is also compatible with the proposed Multiannual Financial Framework 2028-2034, without prejudice to the outcome of interinstitutional negotiations on the Multiannual Financial Framework 2028-2034.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

– ☐ requires a revision of the MFF

3.2.7. Third-party contributions

The proposal/initiative:

– ☑ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year	Year	Year	Year	Year	Year	Year	Total

	2028	2029	2030	2031	2032	2033	2034	
Specify the co-financing body								
TOTAL appropriations co-financed								

3.3. Estimated impact on revenue

– ☑ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[2]						
		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**
Article …….								

For assigned revenue, specify the budget expenditure line(s) affected.

[2] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

High-level description of the requirements of digital relevance and related categories (data, process digitalisation & automation, digital solutions and/or digital public services)

Reference to the requirement	**Requirement description**	**Actors affected or concerned by the requirement**	**High-level Processes**	**Categories**
Requirement 1	Article 7: The Commission will establish, manage and maintain a digital platform (the 'EU Standards Platform') to foster transparency and accountability of the European standardisation system.	European Commission, European standardisation organisations and designated standards development organisations.	The platform will list the standards and standardisation deliverables drafted in support of Union legislation and policies, set out how to access harmonised standards, harmonised standardisation deliverables and standards and standardisation deliverables in support of Union legislation, provide information on standardisation requests and their	Data; process digitalisation and automation; digital solution; digital public service.

			implementation, and provide information on the performance of the European standardisation system. European standardisation organisations and designated standards development organisations shall make available the relevant information on their standardisation activities relating to requested standards and standardisation deliverables to the Commission through an interoperable IT system to ensure the accuracy of information provided on the EU Standards Platform. The information shall be provided in a timely, structured and machine-readable manner, using common identifiers, metadata, models and status controlled	

			vocabularies to ensure its traceability and linkage to relevant Union legislation.	
Requirement 2	Article 6(1): European standardisation organisations and designated standards development organisations shall endeavour to develop requested standards and standardisation deliverables using digital development tools and shall make them available in electronic form and machine-readable format.	European standardisation organisations and designated standards development organisations	European standardisation organisations and designated standards development organisations should ensure that requested standards and standardisation deliverables are available in electronic and, where appropriate, structured machine-readable form, with metadata supporting their identification, versioning, traceability and reuse.	Data; process digitalisation and automation; digital solution.
Requirement 3	Article 6(2): European standardisation organisations and designated standards development organisations shall ensure that the machine-readable format of	European standardisation organisations and designated standards development organisations	European standardisation organisations and designated standards development organisations shall ensure that machine-readable representations	Data; process digitalisation and automation; digital solution

	requested standards and standardisation deliverables are interoperable.		and associated metadata support semantic and technical interoperability, digital exchange and automated processing.	
Requirement 4	Article 5: European standardisation organisations and designated standards development organisations shall provide within the Union unrestricted free online access to referenced standards and standardisation deliverables and shall ensure that referenced standards and standardisation deliverables are available in a readable, searchable, printable and electronically accessible format.	European standardisation organisations and designated standards development organisations	European standardisation organisations and designated standards development organisations shall develop repositories of referenced standards and standardisation deliverables that allow any user to consult, print the document and shall ensure the compliance with the web accessibility Directive.	Data; process digitalisation and automation; digital solution

4.2. Data

High-level description of the data in scope

Type of data	Reference to the requirement(s)	Standard and/or specification (if applicable)
The data in scope for the EU Standards Platform includes identification and metadata for requested standards and standardisation deliverables: title, reference number, version, status, adoption/publication/withdrawal dates, responsible organisations, links to relevant Union acts or policy areas, access conditions/format, lifecycle data for standardisation requests/deliverables, and performance indicators (e.g. timeliness, responsiveness, uptake).	Requirement 1	Technical specifications open, documented and reusable metadata model, (common identifiers and controlled vocabularies. XML/, JSON) or other appropriate serialisations, together with documented machine-to-machine interfaces, will support automated exchange. Relevant European Interoperability Framework (EIF) and Interoperable Europe solutions will be assessed and reused where appropriate.
Structured content of requested standards and standardisation deliverables, including normative provisions, definitions, tables, references and associated metadata, in formats suitable for digital processing, exchange and reuse.	Requirements 2 and 3	The requirement fosters the exchange of data between participants in the standardisation process, as managed by European standardisation organisations and designated standards development organisation, including for example draft texts, structured content components, structured document schemas, and metadata in formats permitting digital processing, search, and automated reuse (e.g. XML).

Alignment with the European Data Strategy

Explanation of how the requirement(s) are aligned with the European Data Strategy

Requirement 1 aligns with the European Data Strategy by increasing availability, visibility, and cross-border reuse of standards data, replacing fragmented channels with a trusted, interoperable digital platform that supports transparency, accountability, and evidence-based policymaking.

Requirements 2 and 3 align with the European Data Strategy by promoting born-digital, structured data over unstructured documents, enabling discoverability, computational processing, and integration with compliance systems, databases, and public services.

Alignment with the once-only principle

Explanation of how the once-only principle has been considered and how the possibility to reuse existing data has been explored

The once-only principle is applied to Requirement 1 by reusing existing data from Commission services, European standardisation organisations, and designated standards development organisations, avoiding duplicate requests for metadata already held in source systems (e.g. standardisation requests, adoption records, or performance reports).

Explanation of how newly created data is findable, accessible, interoperable and reusable, and meets high-quality standards

The once-only principle is applied to Requirements 2 and 3 through single-source digital authoring, where content is created once in structured form and reused across review, adoption, publication, and platform integration, avoiding manual reformatting or duplicate encoding.

Data flows

High-level description of the data flows

Type of data	**Reference(s) to the requirement(s)**	**Actors who provide the data**	**Actors who receive the data**	**Trigger for the data exchange**	**Frequency (if applicable)**
The data in scope for the EU Standards Platform includes identification and metadata for requested standards and standardisation	Requirement 1	European Commission, European standardisation organisations and designated standards development	European Commission	Adoption, amendment, withdrawal of standardisation requests; development, adoption, revision of standards; and	Event-driven for changes (near real-time) and performance data, with periodic consolidation of performance data (quarterly/annually)

deliverables: title, reference number, version, status, adoption/publication/withdrawal dates, responsible organisations, links to relevant Union acts or policy areas, access conditions/format, lifecycle data for standardisation requests/deliverables, and performance indicators (e.g. timeliness, responsiveness, uptake).		organisations		periodic performance reporting	
Machine-readable standards and standardisation deliverables, together with associated metadata	Requirement 2 and 3	European standardisation organisations and designated standards development organisations	European Commission and, subject to applicable access conditions, users of the EU Standards Platform	Delivery, referencing, revision or withdrawal of a standard or standardisation deliverable	Event-driven

4.3. Digital solutions

High-level description of digital solutions

Digital solution	Reference(s) to the requirement(s)	Main mandated functionalities	Responsible body	How is accessibility catered for?	How is reusability considered?	Use of AI technologies (if applicable)
EU Standards Platform	Requirement 1	It will bring together all the information relevant to the development of requested standard and standardisation deliverables, including the status of their development (requested, delivered, assessed or rejected), the links to relevant legislation and essential requirements they aim to cover as well as the relevant contextual information. In addition, the EU standard	European Commission	The platform shall comply with applicable Union accessibility requirements. Machine-to-machine access shall complement, and not replace, accessible human-readable interfaces.	Building on the current eNorm project and reuse common Commission building blocks, documented APIs and relevant Interoperable Europe solutions. Its metadata models and interfaces should be documented and reusable.	

		platform will serve as a performance monitoring tool and will display key performance indicators of the European standardisation system, based on data collected by the Commission, European standardisation organisations and designated standards development organisations.				

For each digital solution, explanation of how the digital solution complies with applicable digital policies and legislative enactments

Digital solution #1

Digital and/or sectorial policy (when these are applicable)	**Explanation on how it aligns**
AI Act	n.a.
EU Cybersecurity framework	n.a.
eIDAS	n.a.

Single Digital Gateway and IMI	n.a.
Others	

4.4. Interoperability assessment

High-level description of the digital public service(s) affected by the requirements

Digital public service or category of digital public services	**Description**	**Reference(s) to the requirement(s)**	**Interoperable Europe Solution(s)**	**Other interoperability solution(s)**
Access to public information on European standardisation	Provide up to date and transparent information on the standards and standardisation deliverables in support of Union legislation and policies and on the performance of the European standardisation system	Requirement 1	DCAT-AP	The EU Standards Platform will require interactions between the Commission, European standardisation organisations and designated standards development organisations. It should build on eNorm and use common identifiers (common metadata model, controlled vocabularies, documented machine-to-machine interfaces) and |relevant Interoperable Europe Portal solutions. European Legislation

				Identifier references should be used, where appropriate, to link standards information to Union legislation. It is likely to have a direct and positive effect on cross-border interoperability because it will function as a common digital reference point for standards-related information. In practice, the platform could reduce fragmentation by acting as a single authoritative source – instead of or complementing the multiple online portals of individual national standardisation bodies.

Impact of the requirement(s) as per digital public service on cross-border interoperability

Digital public service #1

Assessment	**Measure(s)**	**Potential remaining barriers (if applicable)**
Alignment with existing digital and	Prolongation of the current eNorm project.	//

sectorial policies. Please list the applicable digital and sectorial policies identified		
Organisational measures for a smooth cross-border digital public services delivery. Please list the governance measures foreseen	Prolongation of the current eNorm project.	//
Measures taken to ensure a shared understanding of the data. Please list such measures	Use of Interoperable Europe Framework.	//
Use of commonly agreed open technical specifications and standards. Please list such measures	Use of Interoperable Europe Framework.	//

4.5. Measures to support digital implementation

High-level description of measures supporting digital implementation

Description of the measure	**Reference(s) to the requirement(s) of digital relevance that it supports**	**Commission role** (if applicable)	**Actors to be involved** (if applicable)	**Expected timeline** (if applicable)
Build EU Standard platform on current eNorm project	Requirement 1	The Commission shall implement this measure.	European standardisation organisations; designated standards development	The EU standard platform should be operational at the latest at the date of entry into application of the

			organisations.	Regulation, planned for 2028 or 2029.