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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

(Text with EEA relevance)

EN

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Standardisation is a cornerstone 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) as part of the European Product Package, alongside reforms to the New Legislative Framework(5) ('NLF') and Regulation (EU) 2019/1020 of the European Parliament and of the Council(6).

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, civil society, and research and innovation stakeholders, risk 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

(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) 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).
(6) 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, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

Court of Justice of the European Union ('CJEU')[7] 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 *Comité européen des normes* ('CEN'), the *Comité européen des normes électrotechniques* ('CENELEC') and the *European 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 NLF, 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[8] and the Clean Industrial Deal[9]), and sectoral industrial strategies (*e.g.*, housing[10], bioeconomy[11]).

Key amendments to Regulation (EU) No 1025/2012 include:

- the 2022 revision[12], 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[13], 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

(7) Judgment of 27 October 2016, James Elliott Construction Ltd v Irish Asphalt Ltd., C-613/14, EU:C:2016:821; Judgement of 5 March 2024, Public.Resource.Org and Right to Know v Commission, C-588/21 P, EU:C:2024:201.
(8) COM(2019) 640 final, 11.12.2019.
(9) COM(2025) 85 final, 26.2.2025.
(10) COM(2025) 991 final, 16.12.2025.
(11) COM(2025) 960 final, 27.11.2025.
(12) Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 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).
(13) Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications (COM/2025/503 final) and Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications (COM(2025) 504 final).

with the Union's democratic values, but poses financial challenges for European standardisation organisations, particularly CEN and CENELEC, whose revenue rely partly on the sale of harmonised standards. ETSI, which already 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.

- **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 European Product Package, which 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(14) and Regulation (EU) 2024/2847 of the European Parliament and of the Council(15), 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(16) 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(17), 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 competitors 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, civil society, and consumers and benefit from the participation of the research and innovation stakeholders.

(14) 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).

(15) 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).

(16) COM(2021) 118 final, 9.3.2021.

(17) COM(2022) 31 final, 2.2.2022.

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.

• 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 standard 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 revised Regulation will support the implementation of key Union policies while maintaining the voluntary nature of harmonised standards and other standards in support of Union legislation.

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 adapted 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 foster the responsiveness of the European standardisation system rely on the current framework for European standardisation and aim at improving the performance of the European standardisation organisations, while introducing the possibility to rely on designated standard 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 standard development organisations to improve the inclusiveness of the European standardisation process but target these requirements to the national level where the barriers to participation to standardisation are the highest. The requirement to provide free and unrestricted access to referenced standards is necessary to achieve the objective of the initiative and is balanced with the necessity to maintain a financially viable 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 only 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 possible 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, that 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 standard 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[(18)] aimed to assess its performance and impact between 2013 and 2023, in particular by assessing whether standards requested by the Commission in accordance with the Regulation have been delivered in an effective, inclusive and timely manner. The evaluation provided an evidence-based assessment of the effectiveness, efficiency, coherence and relevance 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 the standards-setting process was made faster (from a baseline of more than nine years to six years currently), that conflicting national standards were removed in favour of European standards, that 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 remains too slow, on average six years, and often misses legislative deadlines. This confirms 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

(18) Evaluation of Regulation (EU) No 1025/2012 on European standardisation, SWD(2025) 170 final, 23.6.2025.

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, validating the proposal's focus on improving inclusiveness to ensure higher-quality standards. 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, 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.

- **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 clear 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 standard 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 in a way that would threaten their revenue models, for instance through publication of standards in the *Official Journal of the European Union*. 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 caution in introducing the possibility 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 standard 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 standard development organisations than the three European standardisation organisations and through common specifications, and clearer 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[19] and on a study supporting the impact assessment, both conducted by external contractor[20]. The Commission also frequently 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 improved to incorporate the Boards' 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 include better use of technical specifications developed outside the European standardisation organisations by other standard development organisations, the introduction of the possibility to grant presumption of conformity to standardisation deliverables until a harmonised standard becomes available and a horizontal framework for

(19) 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.

(20) [reference to be added].

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 binding 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 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 standard development organisations in case European standardisation organisations do not deliver, do not meet quality or timing expectations, or where a standard development organisation is objectively better placed to develop the requested standards. The second measure would provide free and unrestricted access to referenced standards through repositories managed by the European standardisation organisations and designated standard development organisations where relevant. This option also strengthens inclusiveness at national level, creates a Chief Standardisation Officer supported by an Expert Centre on European Standardisation and introduces targeted derogations from the 'international first' principle in strategic or sovereignty-sensitive cases. Compared with Option 1, this option is more effective to improve responsiveness, 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 direct effect on average delivery times is expected to remain limited overall, since recourse to alternative standard 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. On international influence, it is more effective 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 standard development organisations for each request. It would establish a Union 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 standard 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 standard 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 equips the Union better 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 savings for businesses estimated at EUR 295 million per year, linked to savings in compliance costs for businesses 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 are estimated at approximately EUR 30 million per year in savings 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, are accompanied by administrative and compliance costs. Ensuring free and unrestricted access to harmonised standards access could reduce national standardisation bodies revenues by up to EUR 30 million annually, particularly affecting those national standardisation bodies that are more reliant on the sales of harmonised standards for financing their activities. The Impact Assessment estimates that EUR 6 million support from the Union budget to the most affected national standardisation bodies could be necessary to ensure their viability. Additional costs would also arise from additional inclusiveness requirements: the related obligations for NSBs are estimated at around EUR 1,9 million per year. The use of alternative standard development organisation to deliver standards in support of Union legislation and policies could generate duplication costs for industry to engage in potential parallel standardisation processes or monitor multiple standard-setting channels, estimated at of EUR 4,5 million per year. The implementation of Option 2 would also require 7,5 additional FTEs, in the Expert Centre 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 2 additional external staff.

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 of EU products and services. However, such effects directly depend on the sectoral legislation and on the definition of essential requirements. A more effective standardisation system would enhance the ability of sectoral legislation to achieve environmental and social objectives.

- **Regulatory fitness and simplification**

This initiative is not part of the Regulatory Fitness Programme (REFIT) but 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 a simplification tools in themselves for businesses to access the internal market. Faster availability of harmonised standards 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 simplify 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 of the European standardisation system, 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 standards development can give EU firms 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 will improve the relevance of standards and supports the uptake of new technologies, including by SMEs. 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

The proposal requires the use of operational appropriations that are commensurate to the current budget allocated to standardisation activities within the Single Market Programme. All activities, in particular all new activities created by the proposal, will be financed under the corresponding envelope within the Single Market and Customs Programme. No additional appropriations are required, provided the envelope allocated to standardisation in the Single Market and Customs Programme is equivalent to the current envelope allocated to standardisation within the Single Market Programme. This would amount to an estimated EUR 165 998 million over the programming period 2028-2034, at constant price, based on annual expenditures for standardisation within the Single Market Programme of EUR 23 714 million in 2027.

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 could be necessary to ensure the financial sustainability of all national standardisation bodies, and of the European standardisation system overall. The annual cost to support the national standardisation bodies most financially exposed to the free access to standards is estimated at EUR 6 million in the Impact Assessment. Such support could be granted by the Commission through an increase in operating grants to European standardisation organisations which would then distribute it across relevant national standardisation bodies. This increase in operating grants would be financed through redeployment within the Single Market and Customs Programme by decreasing by a corresponding amount the action grants financed by the Single Market and Customs Programme to finance experts' participation to standardisation.

The proposal provides for the creation of Centre of Excellence on European Standardisation, led by a Chief Standardisation Officer, to support its implementation as well as the reinforcement of the network of Commission staff involved in requesting and assessing standards in support of Union legislation and policies, along with experts from relevant Union Agencies and Member States. The Expert Centre would host the new tasks of the Commission stemming from the proposal, in particular concerning requests to designated standard development organisations and the improvement of the coordination of EU actors in international standardisation. It would also improve the coordination of the internal network of standardisation experts across Commission services. The Expert Centre would gather a total of 20 FTEs with a central support and coordination role. The additional resource needs to implement the proposal would be covered through internal redeployments within DG GROW (1,5 FTEs), internal redeployments within the Commission DGs relying on the Standardisation Regulation to support their legislation and policies (4 FTEs) and through 2 additional external FTEs, financed under the administrative line of the Single Market and Customs Programme.

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 standard 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 standard 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 three years after its entry into force, and every five years thereafter, as well as an evaluation of the impact of the new flexibilities introduced by 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 requesting and developing standards and standardisation deliverables in support of Union legislation and policies, the functioning of the European standardisation system through the cooperation between the actors involved, the participation of European stakeholders in standardisation and 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,* or by other means as provided for in the relevant Union legislation they aim to support.

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 standard development organisations. It sets out that the development of such standards and standardisation deliverables be transparent and that referenced standards and standardisation deliverables 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 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, to foster the harmonising effect of European standards.

Section II addresses the inclusiveness of the standardisation process by European standardisation organisation and national standardisation bodies. It requires them to facilitate 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.

Chapter IV sets out the framework for requesting standards and standardisation deliverables from designated standard development organisations. It sets out the procedure and requirements for designating standard 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 standard development organisations and the implementation of the request by standard development organisations, similar to the procedure for European standardisation organisations. It specifies that the Commission assesses the coherence of standards and standardisation deliverables from other designated standard 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 mechanism to alert, and, where necessary, withdraw the references to a referenced standard or standardisation deliverable or common specification, which does not satisfy the requirements it aims to cover.

Chapter V outlines the importance of international standardisation and sets out European coordination therein, as well as the requirement that European standardisation organisations and designated standard development organisations inform the Commission of cooperation agreements with other standard development organisations which may affect their standardisation activities as regards the development of standards and standardisation deliverables to support Union legislation and policies.

Chapter VI establishes the position of Chief Standardisation Officer and the Centre of Excellence on European Standardisation, as well as 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 also includes the repeal of Decisions 2014/188/EU, 2014/771/EU, (EU) 2015/1302, (EU) 2016/120, (EU) 2016/1765, (EU) 2017/168, (EU) 2017/1358 and (EU) 2017/2288.

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) [Standardisation for competitiveness] 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 voluntary 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 produce positive economic effects for both businesses and consumers. They increase competition, foster economies of scale, maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing safety and value for consumers. Standards are also an essential building block of the innovation process, allowing research and innovation results to spread and turn into market-ready solutions, and contributing to the competitiveness of market operators.

(2) [Standards for internal market] European standardisation plays a fundamental role in the establishment and functioning of the internal market, by providing common technical solutions which facilitate the free movement of goods and services across Member States, strengthen interoperability, reduce transaction costs and promote effective competition. Through the development of standards and standardisation deliverables, economic operators are enabled to place products and services on the market based on transparent and predictable technical frameworks, thereby fostering innovation, investment and economies of scale. In particular, standards have been at the core of the harmonisation of the internal market under the New Legislative Framework[(2)] adopted in 2008. Regulation (EU) No 1025/2012 of the European

(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:

Parliament and of the Council[3] established the legal framework for European standardisation and organises the cooperation between the Union and the three European Standardisation Organisations listed in Annex I to that Regulation, and which are the *Comité européen des normes* ('CEN'), the *Comité européen des normes électrotechniques* ('CENELEC') and the European Telecommunication Standards Institute ('ETSI').

(3) [Standards for industrial/Union policy] European standardisation is also essential to the Union's industrial policy objectives including the green transition, the digital transformation, industrial resilience and preparedness, and economic security. It supports the implementation of Union legislation and policies in areas such as decarbonisation, circularity, cybersecurity, artificial intelligence, critical technologies and sustainable resource use and contributes to a high level of protection of health, safety, the environment and consumer protection by giving effect to the Union's policy objectives through technical requirements and test methods applied consistently throughout the internal market. Standardisation can provide a first-mover advantage in international technological races, by facilitating the adoption of new technologies and providing a competitive edge to industrial ecosystems.

(4) [Standards for strategic autonomy] European standardisation also contributes to the Union's global competitiveness by supporting access to international markets and by enabling the Union to project its regulatory and industrial interests in global standard-setting processes. European standardisation reinforces the global competitiveness of European industry 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'). In a context of increasing global competition and technological transformation, European standardisation and the Union's participation to international standardisation impact its competitiveness, economic security, strategic autonomy and global relevance.

(5) [Definition of standards] Standards and standardisation deliverables can cover various issues, such as standardisation of different technical characteristics of products, services, processes, systems or entities, in particular where compatibility and interoperability with other products, services, processes, systems or entities are essential. These can notably specify certain characteristics of a product or service, such as levels of quality, performance, security, interoperability, environmental protection, health, safety or dimensions and can also specify the testing, test methods and criteria for assessing the performance of products, services, processes, systems or entities, notably in relation to essential requirements laid down in Union legislation.

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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), 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).

(6) [Article 2 - Typology of standards in support of Union] Standards and standardisation deliverables can support Union legislation and policies in several ways. These can be requested to give effect to essential requirements set out in Union legislation under the New Legislative Framework and provide a presumption of conformity for products and services designed in accordance with such standards once the reference to these standards have been published in the *Official Journal of the European Union*. Such harmonised standards simplify making products and services available on the internal market and reduce compliance and conformity assessment costs for businesses. Standards can also support the implementation of Union legislation, such as Regulation (EU) 2024/3110[4] by laying down test methods and criteria for assessing compliance which can be mandatory, or more generally by turning legislative requirements into technical specifications, such as for Directive (EU) 2016/797[5] of the European Parliament and of the Council or the public procurement act[6]. Furthermore, standards and standardisation deliverables support the implementation of the Union's industrial policy initiatives as building blocks for competitive industrial ecosystems.

(7) [Limitations of 1025/2012] Regulation (EU) No 1025/2012 has provided for the uptake of European standards to support Union legislation and policies by organising the cooperation within the European standardisation system, between the actors involved in developing European standards, namely the Commission, the European standardisation organisations, national standardisation bodies of Member States, as well as market operators and stakeholders. However, the current framework is unfit to enable the European standardisation system to keep up with rapid technological changes and growing global competition. Delays in the availability of harmonised standards, insufficient participation of relevant stakeholders and the gradually declining influence of Union stakeholders in international standardisation impair the ability of the European standardisation system to contribute to the Union's strategic objectives and to the functioning of the internal market. Furthermore, the framework of Regulation (EU) No 1025/2012 no longer aligns with the increasing number of Union legislation and policies relying on standards, which now includes digital technologies, cybersecurity, artificial intelligence, clean tech and strategic value chains. Moreover, it is unfit to meet new challenges within the standardisation landscape such as the product-service convergence, the uptake of standardisation deliverables other than standards and the increasing relevance of standard development organisations other than the European standardisation organisations in certain specialised sectors. Furthermore, the requirements for public access with respect to harmonised standards derived from the case law of the Court of Justice[7] put in question the current functioning of European standardisation organisations, thereby underlining the need for a clearer and more modern legal framework to ensure the long-term viability of European standardisation in support of Union legislation and policies.

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(4) 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).

(5) 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).

(6) [Reference to the Commission's proposal on PPA to be added].

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

(8) [Policy objectives] The current legal framework should be simplified and adapted to reflect those developments while maintaining a viable European standardisation system fit for addressing challenges in the field of standardisation. The European Council Conclusions of March 2026[8] 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[9] and the Single Market Strategy of April 2025[10] which identified the slow and unpredictable standardisation process in support of Union legislation and policies as one of the main barriers to the internal market. Therefore, it is necessary to modernise the European standardisation system to improve its responsiveness and ability to deliver standards in support of Union legislation and policies in a rapid, timely, inclusive and transparent way, while preserving the role of standardisation as a voluntary and market-driven tool. In order to ensure the effectiveness and efficiency of the European standardisation system, it is also necessary to ensure its long-term viability and its ability to deliver standards that are accessible, in line with the case law of the Court of Justice. The European standardisation system should also preserve its international influence to promote the Union's international competitiveness.

(9) [EPA approach] Standards are a key instrument in supporting the efficient and effective implementation of the New Legislative Framework. It is therefore appropriate to modernise Regulation (EU) No 1025/2012 in parallel and in coherence with the proposed European Product Act[11], which together form the European Product package. The European Product package modernises the Union's product legislation framework by creating a single set of rules for product legislation.

(10) [Article 1 – Subject matter] In order to ensure a coherent framework for developing standards and standardisation deliverables in support of Union legislation and policies, this Regulation should lay down rules for requesting, developing and assessing such standards and standardisation deliverables. As common specifications pursue the same objectives as standards requested by the Commission to support Union legislation, this Regulation should also provide for a coherent framework for common specifications across Union legislation in this Regulation, thereby complementing the horizontal approach introduced in the future Regulation and Directive on digitalisation and common specifications[12], which amend several of the Union's product acts to implement a fallback procedure for the Commission to adopt common specifications. To foster a high-quality European standardisation system, this Regulation should also cover the participation of stakeholders and the interaction between European standardisation organisations, national standardisation bodies, Member States and the Commission, as well as with standard development organisations designated under this Regulation, given their increasing relevance in certain specialised sectors.

(8) EUCO 1/26, European Council meeting (19 March 2026) – Conclusions.
(9) COM(2025) 30 final, 29.1.2025.
(10) COM(2025) 500 final, 21.5.2025.
(11) [Reference to European Product Act to be added]
(12) Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications (COM/2025/503 final) and Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications (COM(2025) 504 final).

Nevertheless, this Regulation should be without prejudice to other applicable sectorial rules laid down by Union legislation. Additionally, Union legal acts might directly reference a standard or a standardisation deliverable, insofar as it complies with requirements established by the case-law of the Court of Justice of the European Union[13].

(11) [Article 1 – Scope / EMPL/COMP] The legal framework allowing the Commission to request standards and standardisation deliverables to support Union legislation and policies 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 standard development organisations should also refrain from conducting standardisation activities that could affect such rights. Furthermore, European standardisation organisations and standard development organisations 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).

(12) [Article 3(1) – Principles] Standards and standardisation deliverables requested by the Commission should comply with the World Trade Organization ('WTO') 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 view of all parties concerned but does not require unanimity. Standardisation in support of Union legislation and policies should also guarantee a high level of inclusiveness through the involvement of all relevant interested parties, including small and medium-sized enterprises (SMEs), civil society representatives, in particular representing environmental, social and consumer interests, research and innovation stakeholders and public authorities. Such participation fosters a high level of market adoption and high quality of standards and standardisation deliverables in support of Union legislation and policies that reflect societal and market needs.

(13) [Article 3(2) – Public/private objectives] Given the important role standards and standardisation deliverables play in supporting the internal market and the implementation of Union legislation and policies, they should be market-driven, whereby the needs of economic operators and stakeholders directly or indirectly affected by such standards are duly acknowledged, while taking into account the public interest and the objectives of the Union legislation and policies they are supporting, such as competitiveness, innovation, sustainability, health and safety, and economic security. Standards and standardisation deliverables in support of Union legislation and policies should aim at balancing market needs and societal objectives such as security, climate and environmental sustainability, health and safety and contribute to advancing the Union's values and fundamental rights, in particular accessibility and gender equality.

(14) [Article 4 – Transparency of establishment] Standards and standardisation deliverables should be developed and adopted in compliance with the principles of transparency and accountability, taking into account their relevance for the implementation of

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(13) Cf. Judgment of 21 April 2026, Nederlandse Voedsel- en Warenautoriteit and Others v Stichting Rookpreventie Jeugd, C 155/24, EU:C:2026:327.

Union legislation and policies. Accordingly, European standardisation organisations and designated standard development organisations should make available to the public on their website the list of all stakeholders participating in the development of each requested standard and standardisation deliverable, including organisations, associations, groups and self-employed individuals, acting on their own behalf or on behalf of other organisations, and the interests they represent.

(15) [Article 5 – Access/scope] Standards and standardisation deliverables requested in support of Union legislation and policies, the references of which have been published in the *Official Journal of the European Union,* or by other means as provided for in the relevant Union legislation, 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 [within the Union] to the public free of charge, in a general, effective and non-discriminatory manner through a readable, searchable, printable [, downloadable] and electronically accessible format. [Access should also be given to interested parties outside the Union which can demonstrate a legitimate interest]. European standardisation organisations and designated standard development organisations should therefore ensure that such access is provided without unjustified barriers such as mandatory pre-identification or subscription and remains available after the reference has been withdrawn. That access should be in line with Directive (EU) 2016/2102[(14)] and Directive (EU) 2017/1564[(15)] of the European Parliament and of the Council. Furthermore, where standards and standardisation deliverables were adopted under Regulation (EU) No 1025/2012 before the entry into force of this Regulation, the entire document should be accessible, while under this Regulation access could be limited to parts of the standard, provided they form a self-standing document containing all information necessary to comply with the requirements set out in the relevant Union legislation it supports. Access should be granted without prejudice to the copyrights that the European standardisation organisations and designated standard development organisations may claim to have on the referenced standards or standardisation deliverables.

(16) [Article 6 – Digitalisation] 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 standards development tools and to foster inclusiveness by decreasing the costs of participating in the standardisation process, in particular for SMEs, civil society stakeholders and research and innovation stakeholders. Standards and standardisation deliverables should also be made available in machine-readable format, with the metadata necessary to ensure their identification, traceability and use, to foster their digital exchange and automated processing. Digitalisation also has the potential to improve the quality of standards and standardisation deliverables and 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

(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).

(15) Directive (EU) 2017/1564 of the European Parliament and of the Council of 13 September 2017 on certain permitted uses of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled and amending Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 242, 20.9.2017, p. 6, ELI: http://data.europa.eu/eli/dir/2017/1564/oj).

integration in the business processes of market operators, have great potential to foster the Union's competitiveness. European standardisation organisations and designated standard development organisations should be encouraged to develop such smart standards and should seek convergence in their formulating of smart standards to facilitate their use.

(17) [Article 7 – EU Standards platform] 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 available up-to-date information on requested standards and standardisation deliverables, in particular as regards the status of their development and referencing. Moreover, the EU Standards Platform should provide detailed information on the performance of the European standardisation system and on the implementation of this Regulation. European standardisation organisations and designated standard development organisations should cooperate with the Commission to ensure the information on the EU Standards Platform is accurate and up to date to facilitate public scrutiny of the functioning of the European standardisation system. To ensure the accuracy of the information provided on the EU Standards Platform, the European standardisation organisations and designated standard development organisations should be required to make available to the Commission the relevant information on their standardisation activities under this Regulation via an IT system which is interoperable with that Platform.

(18) [Article 8 – Financing] 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 should support funding the transition to new business models, notably through the Single Market and Customs Programme(16) to strengthen the long-term financial viability of the European standardisation system. Furthermore, the participation of European stakeholder organisations designated under this Regulation as representatives of SMEs, consumers, and environmental and social interests is essential for an inclusive standardisation process and contributes to balancing public and private interests. Thus, the Union should also financially support such European stakeholder organisations through the Single Market and Customs Programme. In addition, the Union may fund concrete actions to develop standards and standardisation deliverables in areas of strategic interest, such as the participation of Union experts to the standardisation process or activities to improve usability and interoperability of standards and standardisation deliverables. Additional funding delivered through the European Competitiveness Fund(17) and the Horizon Europe Programme 2028-2034(18) should also contribute to enhance the responsiveness of the European standardisation system by facilitating participation from industry, SMEs, civil society and research and innovation experts and by bringing innovative technological contributions into the European standardisation system, especially for priority standardisation activities requested by the Commission.

(19) [Article 9 – AUWP] The responsiveness of the European standardisation system, in particular its ability to deliver standards and standardisation deliverables in time to

(16) COM(2025) 590 final, 3.09.2025.
(17) COM(2025) 555 final, 16.07.2025.
(18) COM(2025) 543 final, 16.07.2025.

facilitate market operators' compliance with Union legislation when they enter into force, 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. It should contribute to start standardisation work as soon as a need has been identified and should be a coordination tool, allowing the European standardisation organisations and designated standard development organisations to prepare for possible standardisation activities to support Union legislation and policies and to reply swiftly to standardisation requests. 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.

(20) [Article 10 – Designation of ESOs] The European standardisation system is primarily organised by and for the stakeholders concerned 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, covering a wide range of sectors, ensuring a high-level of inclusiveness, quality, representation and influence of Union stakeholders, contributing 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 standards in their respective areas of expertise. The European standardisation organisations' processes are recognised and trusted by market operators, and they have built the expertise to deliver standards to support Union legislation and policies over the past decades. Thus, those European standardisation organisations should remain the main partners of the Union for developing standards and standardisation deliverables to support Union legislation and policies.

(21) [Article 10 – Designations of ESOs/ Amendments] The Commission should be empowered to amend the list of European standardisation organisations in Annex I, as new European standardisation organisations could be designated to reinforce the European standardisation system in specific sectors, provided they represent European stakeholders and interests through the membership of national standardisation bodies from all Member States, are established in the Union and are able to comply with all requirements set out in this Regulation. The Commission should also be able to remove a European standardisation organisation from the list established in Annex I, in particular if it no longer meets the requirements set out in this Regulation or fails to perform at a sufficient level over a sustained period, as monitored by a framework of key performance indicators. To that end, the Commission should regularly assess the performance of European standardisation organisations and engage with the European standardisation organisation concerned as soon as it identifies underperformance and strives to jointly identify solutions to remedy the situation before removing the European standardisation organisation concerned from Annex I.

(22) [Article 11 – National standardisation bodies] 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 standards and standardisation deliverables to support Union legislation and policies. Member States should notify the Commission of the independent organisations they appoint as national standardisation bodies, ensuring, 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 national standardisation bodies.

(23) [Article 12 – EU decision-making] National standardisation bodies play an essential role in the European standardisation system and are therefore best placed to ensure that the interests, policy objectives and values of the Union, as well as its public interests, are duly taken into account in the European standardisation organisations. Their role in the decision-making bodies of the European standardisation organisations should be maintained when those bodies take decisions concerning standards and standardisation deliverables requested by the Commission without affecting the important role played by the stakeholder base in preparing effective standards that respond to public interest and market needs. The European standardisation organisations must ensure that formal decisions regarding standards and standardisation deliverables in support of Union legislation and policies are taken exclusively by national standardisation bodies, in order to guarantee European decision-making for such standards and standardisation deliverables. The European standardisation organisations should facilitate the participation of the Commission, including its agencies, in their governance and technical bodies, in particular their working groups and technical committees, in order for the Commission to facilitate the development of requested standards and standardisation deliverables that comply with the requirements set out in the standardisation request and satisfy the requirements set out in Union legislation which they aim to cover. European standardisation organisations should ensure that the participation of liaison technical bodies and liaison organisations does not impede the timely and efficient drafting of requested standards and standardisation deliverables.

(24) [Article 13 – Key performance indicators] 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 quality of standards and standardisation deliverables delivered to support Union legislation and policies, the inclusiveness of the 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. Financing of European standardisation organisations by the Union budget should be adapted to their performance in implementing this Regulation, based on the key performance indicators.

(25) [Article 14 – Cooperation Commission / ESOs] The successful cooperation between the Commission, the relevant Union agencies and the European standardisation organisations is essential to 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 Commission and the European standardisation organisations should cooperate beyond standards and standardisation deliverables requested to support Union legislation and policies, to foster the development of European standards and European standardisation deliverables that contribute to the Union’s competitiveness and core values.

(26) [Articles 15 and 16 – Transparency of European standards] Within the Union, 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 European standards. Therefore, European standardisation organisations, national standardisation bodies and the Commission should engage in exchanging information about current and future standardisation activities and national

standardisation bodies should apply the standstill principle, which requires them to withdraw national standards after adoption of a new European standard covering the same scope. That exchange of information should, nevertheless, 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].

(27) [Article 17 – Stakeholder participation] The quality, legitimacy and public acceptance of European standardisation depend on the appropriate and effective participation of all relevant stakeholders. European standardisation organisations should promote increased participation and an inclusive process, in the interest of the entire standardisation system. In their standardisation activities, European standardisation organisations should enable that all relevant stakeholders, including SMEs, consumer organisations, environmental and social stakeholders, research and innovation stakeholders as well as public authorities, are properly represented and can take part effectively.

(28) [Article 17 – Industry and SMEs experts participation] 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 increase the relevance of standards for SMEs and to promote their market uptake by all relevant market operators.

(29) [Article 17 – Societal stakeholders] Standards have a broad societal impact: they influence citizens' safety and well-being, the environment, workers' safety and working conditions, the inclusion of people 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 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 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.

(30) [Article 17/19 – R&I stakeholders/Commission research facilities] Standards are also a key part of the innovation value chain and facilitate the diffusion of new technologies. Therefore, research and innovation actors, such as researchers, academics, research centres, start-ups and scale-ups, should be actively involved in European standardisation, because their participation enhances the technological relevance and neutrality of standards and promotes the uptake and valorisation of research results

(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).

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, as it can provide useful evidence on emerging technological developments. Scientific evidence and research results are important to ensure that standards and standardisation deliverables support competitiveness and societal needs, including sustainability, health and safety and security. The Commission research facilities and relevant Union agencies play an important role in ensuring 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 the European standardisation organisations should facilitate their access to the relevant standards to conduct this work.

(31) [Article 17 – OSOs stakeholders] 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, competition, interoperability, transparency, and supporting digital sovereignty within the Union. Open source and open standards are complementary instruments for fostering interoperability, innovation, transparency and technological resilience within the Union. Open source can reduce vendor lock-in, reduce dependencies, support collaboration across borders and sectors, and facilitate the efficient re-use of digital solutions, including in the public sector. They can also contribute to security and resilience, since open scrutiny may help identify and remedy vulnerabilities more rapidly. In line with the EU Open Source Strategy[21], 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. Promoting cooperation, coherence and complementarity between open-source and standardisation can therefore strengthen the digital single market, reduce dependency on proprietary solutions, support competition and enhance the Union's capacity to develop and maintain trustworthy digital infrastructures. It is also important to ensure compatibility between open source and standardisation intellectual property policies to foster such cooperation.

(32) [Article 17 & 21 – Public authorities] 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. Their involvement contributes to better aligning technical specifications and legal requirements and reduces the risk of non-compliance or rejection of the delivered standards and standardisation deliverables.

(33) [Article 18 – European stakeholders organisations] Coordination and representation of SMEs and societal interests, which may vary across the Union, represent a challenge to the European standardisation process. As their participation is essential for the quality of standards and standardisation deliverables supporting Union legislation and policies, the role and the input of societal stakeholders and SMEs in the development

(21) COM(2026) 503 final, 03.06.2025.

of such standards should be strengthened. In order to facilitate the coordination of such interests across the Union and to guarantee the effective representation of such interests that might otherwise be underrepresented in the standardisation process, the Commission should designate European stakeholder organisations representing SMEs, consumers, environmental interests and social interests. The organisation representing the interests of consumers should sufficiently represent and include the interests of people with disabilities. 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. Given their importance to promote the quality of standards in support of Union legislation and policies, the Commission should select the organisations empowered to represent SMEs, consumers, environmental and social interests based on objective criteria and a transparent and non-discriminatory process, for a duration of up to four years, to ensure their ability to build up the necessary skills and competences. 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 to encourage and facilitate the representation and effective participation of such stakeholders does not necessarily entail any voting rights for such stakeholders. However, European standardisation organisations should make their best effort to take the comments of such organisations into account and to explain, where relevant, how they have been taken into consideration in the standard or standardisation deliverable being developed. Designated standard development organisations should also ensure that these organisations can effectively contribute to the development of requested standards and standardisation deliverables.

(34) [Article 20/21 – National inclusiveness] National standardisation bodies play an essential role in fostering the appropriate and effective participation in the European standardisation system for all 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 also enable the effective participation of relevant stakeholders, including SMEs, consumer organisations, environmental and social stakeholders, research and innovation stakeholders and public authorities. As 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 and provide free access or special rates to such stakeholders. 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.

(35) [Article 22 – Pre-consultation of ESOs] The Commission should consult European standardisation organisations on new standardisation needs that may trigger a standardisation request, for instance 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 form 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 they are able to mobilise in the relevant area and the likely duration of the process. The consultation should also contribute to identify possible specificities in terms of stakeholder participation, inclusiveness requirements, restriction of participation to Union actors or the identification of relevant technical specifications developed or being developed by other standard development organisations. This consultation should serve as a mechanism to improve the responsiveness of the standardisation process by providing the European standardisation organisations and the Commission with the necessary information to prepare a standardisation request, as well as to allow the European standardisation organisations to potentially initiate activities related to the forthcoming request. The Commission should assess the response of the European standardisation organisations to the consultation, or lack thereof, to determine the appropriate actions for the identified standardisation needs. In particular, if the European standardisation organisations have indicated that they would not accept the standardisation request or if, based on the information shared by the European standardisation organisations and based on previous experiences and practices in a given area, the Commission considers that the European standardisation organisations would not be able to deliver a high quality standard or standardisation deliverable in a timely manner, the Commission may prepare a standardisation request to designated standard development organisations or initiate the development of common specifications.

(36) [Article 23 – SReq / process] 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 or revise 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 define with sufficient precision the requirements concerning the content to be met by the requested standards and standardisation deliverables and their possible legal effect. The request should indicate a deadline for the delivery of each relevant standard and standardisation deliverable to be respected by the European standardisation organisations. The standardisation request may also include provisions regarding the revision of the requested standards or standardisation deliverables, in particular due to the evolution of technologies.

(37) [Article 23 – Sreq / harmonised standardisation deliverables] The Commission may also, in particular in areas where the time required to deliver a harmonised standard would be too long and would slow down market uptake, for instance for digital products and services with shorter lifecycle and a high level of innovation, request European standardisation organisations to deliver a harmonised standardisation deliverable covering the relevant essential requirements necessary for providing a presumption of conformity, as a step toward a harmonised standard. Such deliverables should be of high quality, based on an inclusive, open and transparent standardisation process, but may not 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 which provides a presumption of conformity for a given product or service.

(38) [Article 23 – Sreq / PAS] In order to increase the speed of the standardisation process and improve alignment of standards and standardisation deliverables in support of Union legislation and policies with state-of-the-art technical specifications, the Commission may specify in its standardisation request an obligation for European standardisation organisations to take into account identified existing technical specifications from other standard development organisations. European standardisation organisations should be responsible for the agreements with such standard development organisations, where necessary, and ensure that the delivered standards or standardisation deliverables based on existing technical specifications from other standard development organisations comply with the obligations laid down in this Regulation.

(39) [Article 23 – Sreq / requirements on standardisation processes] The Commission may also lay down specific requirements for participation and inclusiveness in its standardisation request. For instance, for standards and standardisation deliverables that support accessibility or that may have an impact on fundamental rights within the Union, it may be essential to ensure the active and effective participation of stakeholders which might not usually be involved in the European standardisation process to ensure that the requested standards or standardisation deliverables are aligned with the Union's values. Furthermore, the standardisation request may introduce some specific requirement as regards participation in the development of standards and standardisation deliverables relating to Union strategic assets, interests, autonomy or 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 in the standardisation request that only certain types of stakeholders may take part in the standardisation process or that the European standardisation process diverges from existing international standards or international standards under development, in order to protect the Union's strategic autonomy and its strategic interests.

(40) [Article 23 – Sreq / requirements for standardisation steps] The standardisation request may also indicate any specific requirements for the standardisation process itself to foster the responsiveness of the standardisation process and to ensure that the Commission can anticipate possible delays in the delivery of standards and standardisation deliverables. The standardisation request may set out the main procedural steps, and their expected 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 standard 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.

(41) [Article 23 – Sreq / consultation of experts] As standardisation requests set out the objectives and procedural requirements for the delivery of requested standards or standardisation deliverables, they should be established in an open and transparent manner and benefit from the contribution of relevant experts. The Commission may in particular consult experts of Member States and should publish draft standardisation

requests on the EU Standards Platform to allow for stakeholders to submit their comments.

(42) [Article 24 – Implementation of SReq] Where a European standardisation organisation has accepted a standardisation request, it should regularly report to the Commission on the activities it undertook and the progress it achieved, generally every year unless otherwise specified in the standardisation request. It should make available to the Commission the relevant drafts and adopted documents in response to the request and should duly take into account comments from the Commission related to possible divergence with the standardisation request to foster compliance. In case the European standardisation organisations are unable to deliver the requested standards and standardisation deliverables within the deadlines set out in the request and the Commission considers the best available option is to continue the implementation of the standardisation request by the European standardisation organisations, the Commission may amend the deadlines or expiry dates *via* a simplified procedure, without having to formally re-consult stakeholders.

(43) [Article 25 – Assessment of Sreq / principle] 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 to conduct the assessment, including, where relevant, normative references, which are documents to which reference is made in the requested standard or standardisation deliverable in such a way as to make them indispensable for the application of the requested standard or standardisation deliverable.

(44) [Article 25 – Assessment of Sreq / positive assessment] When the Commission has assessed that the delivered standard or standardisation deliverable satisfies the essential requirements it aims to cover and complies with the requirements set out in the request, it should publish a reference of the standard or standardisation deliverable without delay in the *Official Journal of the European Union,* or by other means as provided for in the relevant Union legislation. That reference allows market operators to rely on such a standard or standardisation deliverable, either as a harmonised standard or harmonised standardisation deliverable providing a presumption of conformity with Union legislation, or as a standard or standardisation deliverable in support of Union legislation with another potential legal effect set out in the corresponding Union legislation. The Commission should conduct the assessment within six months from the delivery of the requested standard or standardisation deliverable to avoid uncertainties whereby a standard or standardisation deliverable adopted by European standardisation organisations is available to market operators, while its legal effect may not yet be established.

(45) [Article 25 – Assessment of Sreq / negative assessment] If the Commission concludes that the quality of a delivered standard or standardisation deliverable is not adequate, the Commission may reject it or publish the reference of the standard or standardisation deliverable with restrictions, indicating the requirements that are not covered by the standard or standardisation deliverable and for which the standard cannot provide a presumption of conformity or means to comply with the requirements

set out in Union legislation or policies. The Commission should exercise discretion to assess the delivered standard or standardisation deliverable, in particular as regards its 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, thereby further delaying the possibility for market operators to benefit from a presumption of conformity or legal compliance with the corresponding Union legislation.

(46) [Article 25 – Assessment of Sreq / amendments & revision] European standardisation organisations regularly revise or amend European standards and European standardisation deliverables to ensure they keep up with the state of the art. For referenced standards and standardisation deliverables, this should take place in close cooperation with the Commission, as divergences between such revised or amended standards and standardisation deliverables and referenced standards and standardisation deliverables may create uncertainty for market operators.

(47) [Article 26/27 – Designation of SDOs and criteria] In order for the European standardisation system to respond effectively to evolving technological and policy needs, especially where the necessary expertise may not exist within the European standardisation organisations, the Commission should be able to address standardisation requests to other standard development organisations, which are not national nor international standardisation bodies, designated based on objective criteria to ensure their ability to deliver a highly inclusive standardisation process, which can reflect European interests. The Commission should only designate standard development organisations that are able to implement a standardisation process that complies with the principles for European standardisation set out in this Regulation and with best standardisation practices. Designated standard development organisations should in particular ensure the openness, transparency and inclusiveness of their standardisation process, and 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 of the standardisation process and the publicity of interests represented, the participation of Union stakeholders including European societal stakeholders, in particular SMEs, consumers, environmental and social stakeholders. The Commission should pay particular attention to the ability of the designated standard development organisations to facilitate the participation of European stakeholders in the standardisation process and to ensure that, where Union interests are represented, those interests are effectively taken into account. Open source organisations may develop technical specifications that meet the needs of the Union and could be designated as standard development organisations as long as they comply with the criteria set out in this Regulation. Where an organisation can no longer meet the requirements laid down in this Regulation or can no longer effectively serve the interests of the Union, the Commission should withdraw its designation. The Commission should publish the list of designated standard development organisations on the EU Standards Platform.

(48) [Article 28 – integration of SDOs in ESS] In order to ensure that addressing a standardisation request to designated standard development organisations complements the European standardisation system rather than fragments it, appropriate safeguards should apply concerning transparency, information-sharing and cooperation between designated standard development organisations, the European standardisation organisations and the Commission. The designated standard

development organisations should maintain a 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, by providing access to their draft standards and standardisation deliverables developed pursuant to a standardisation request to the European standardisation organisations upon their request. The designated standard development organisations should duly take account of comments addressing issues of coherence between the draft standards and standardisation deliverables with referenced standards and standardisation deliverables received within a reasonable period, especially as regards any comments indicating that a draft requested standard or standardisation deliverable may adversely affect the internal market.

(49) [Article 29 – Sreq to SDOs/triggers] Where the European standardisation organisations have indicated during the consultation that they would not accept the request, or when the Commission has assessed that, based on the consultation, the European standardisation organisations are not in a position to deliver timely and high-quality standards and standardisation deliverables, the Commission may address a standardisation request to designated standard development organisations. The Commission may also address a standardisation request to designated standard development organisations when European standardisation organisations fail to deliver the requested standard or standardisation deliverable or fail to appropriately comply with the standardisation request. Such a decision should be based notably 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 standards or standardisation deliverables with the potential benefits of addressing the request to designated standard development organisations, with the objective of ensuring that a high-quality standard becomes available as soon as possible. In such cases, the Commission should withdraw the standardisation request to the European standardisation organisations to prevent that different standards that address the same essential requirements exist.

(50) [Article 29/30/31 – Sreq to SDOs] As referenced standards or standardisation deliverables developed by designated standard development organisations have the same status as referenced standards and standardisation deliverables developed by the European standardisation organisations in the European standardisation system, the process and requirements for addressing, implementing and assessing standardisation request to designated standard development organisations should be similar as the ones for European standardisation organisations. However, given the particularities of requesting a standard or standardisation deliverable to designated standard development organisations, it is appropriate that standardisation requests to designated standard development organisations should be adopted by the Committee set up by this Regulation in accordance with the examination procedure. For standards and standardisation deliverables developed by designated standard development organisations, the Commission should also assess the coherence of the delivered standards or standardisation deliverables with the relevant referenced standards and standardisation deliverables, the references of which have been published in accordance with this Regulation and Regulation (EU) No 1025/2012.

(51) [Article 32 – Common specifications] This Regulation provides for a horizontal framework that should promote the timely development of harmonised standards by European standardisation organisations, and where appropriate, by designated standard

development organisations. However, where no such a harmonised standard exists, when such a standard, or parts thereof, does not satisfy the requirements which it aims to cover or when the Commission considers that the implementation of the standardisation request does not comply with the request, the Commission should be able to establish common specifications that provide a means to comply with the essential requirements set out in 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. As common specifications pursue the same objectives as the harmonised standards they supplement, it is appropriate that this Regulation set common rules for the conditions and process to adopt common specifications. Such rules should not prejudice sector specific requirements for common specifications as laid down in relevant Union legislation. The Commission should ensure a highly inclusive process to develop common specifications, and consult relevant 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 standard development organisations, when it engages in the preparation of common specifications while a standardisation request is being implemented. When European standardisation organisations, or designated standard development organisations, deliver a standard that covers the same requirements as adopted common specifications, the Commission should assess such a standard without delay. If such a standard 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.

(52) [Article 33 – Safeguards] Member States or the European Parliament should be able to notify the Commission 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 no other Member States or the European Parliament objects to the notification, their reference is restricted or withdrawn, or the common specification repealed. Nevertheless, when one or more Member States or the European Parliament object, 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.

(53) [Article 25 & 34 – De-referencing] Where a European standardisation organisation or a designated standard development organisation decides to withdraw a referenced standard or standardisation deliverable, for instance because it considers that it is no longer in line with the state of the art or with market requirements, it should notify the Commission without delay. The Commission should then consider whether to withdraw the reference to such a standard or standardisation deliverable, with the objective of ensuring predictability for businesses. The Commission may also decide to 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 or the essential requirements it aims to cover.

(54) [Article 35 – International first principle] 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 with international standardisation bodies is an important component of the European standardisation system, it is appropriate to allow for exceptions where international outputs do not correspond to the needs of the Union. The Commission should therefore carefully assess the alignment with international standards and its impact on the Union's competitiveness and strategic autonomy. Based on this assessment, it may be appropriate to restrict the European standardisation process to European actors or actors that share the interests of the Union, or diverge from existing international standards or international standards under development, in order to protect the Union's strategic autonomy and its strategic interests.

(55) [Article 36 – coordination for international] In order to maintain and 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 the strategic use of standards by other global actors. The Union should also promote cooperation between European standardisation organisations and international standardisation bodies and with other standards development organisations when relevant, in particular recognised standards development organisations in their sector of competence.

(56) [Article 38 – CSO and Centre of Excellence] To coordinate standardisation activities, relations with European standardisation organisations and designated standard development organisations and promote a Union approach in international standardisation, the Commission should appoint a Chief Standardisation Officer. That function should contribute to public expertise, technical and strategic support, alignment with Union policies and a coherent Union approach in international standardisation, to better take into account the growing strategic importance of standardisation. The Chief Standardisation Officer should be supported by 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 should serve as a coordinating hub for all 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 standard development organisations, as well as the coordination of sectorial experts, in particular in Member States. 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. The Centre of Excellence should also contribute to promote the Union's influence in standardisation activities at international level.

(57) [Article 39 – Delegation] In order to amend the list of European standardisation organisations, 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[22]. 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.

(58) [Article 40 – Committee] The Committee established pursuant to this Regulation should assist the Commission in matters related to the implementation of this Regulation, having due regard for the views of sectoral experts. Close cooperation between the Commission and the Member States is necessary for the sound functioning of the European standardisation system. The Commission should therefore inform the Member States on a regular basis of the performance of that system, through the committee established under this Regulation, so as to support strategic oversight, facilitate coordination and enable timely follow-up where shortcomings are identified. Given their unique role to contribute to the effective implementation of this Regulation, it is appropriate that European standardisation organisations are observers to the Committee and that designated standard development organisations are invited if relevant.

(59) [Article 40 – Committee procedures] 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[23]. The examination procedure should be used for adopting standardisation requests addressed to designated standard development organisations and for standardisation requests addressed to European standardisation organisations when they include specific requirements introduced by this Regulation, namely the request of harmonised standardisation deliverables, the restriction of participation to the standardisation process to actors representing Union interests and any requirements as regards the standardisation process independently of existing international standards or those under development. 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 decision, as national interest 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.

(60) [Subsidiarity and proportionality] Since the objectives of this Regulation, namely to increase the responsiveness of the European standardisation system, ensure its sustainability and a high-level of participation and promote the Union's influence in international standardisation, cannot be sufficiently achieved by the Member States alone, due to the harmonisation effect of standards and standardisation deliverables in support of Union legislation and policies, 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.

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(22) OJ L 123, 12.5.2016, p. 1.

(23) 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).

(61) [Article 43 – repeals] In the interest of clarity and legal certainty, Regulation (EU) No 1025/2012 should therefore be repealed and replaced by this Regulation.

(62) [Article 44 – entry into force] This Regulation should apply 6 months after its entry into force.

HAVE ADOPTED THIS REGULATION:

Chapter 1
General provisions

Article 1

Subject matter

This Regulation lays down rules with regard to:

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

(b) the cooperation between European standardisation organisations, national standardisation bodies, designated standard 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 standard development organisation, for repeated or continuous application, and compliance with which is not compulsory unless otherwise specified in Union legislation;

(2) 'standardisation deliverable' means any other technical specification than a standard, adopted by a standard development organisation, for repeated or continuous application, and compliance with which is not compulsory unless otherwise specified in Union legislation;

(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) 'harmonised standard' means a standard, developed or revised 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;

(5) 'harmonised standardisation deliverable' means a standardisation deliverable, developed or revised 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;

(6) 'standard and standardisation deliverable in support of Union legislation or policies' means a standard and standardisation deliverable, developed or revised in response to a standardisation request, that does not aim at providing presumption of conformity with Union legislation, and the reference of which has been published in the *Official Journal of the European Union*, or by other means as provided for in the relevant Union legislation;

(7) '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;

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

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

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

(11) 'designated standard development organisation' means a standard development organisation, other than a European standardisation organisation, to which the Commission can address a standardisation request;

(12) 'European stakeholder organisations' means the organisations representing micro, small and medium-sized enterprises ('SMEs'), as defined in Commission Recommendation 2003/361/EC[24], consumers, environmental and social interests to foster the inclusiveness of the European standardisation system, as designated in accordance with this Regulation;

(13) 'referenced standard and standardisation deliverable' means a standard and standardisation deliverable developed or revised in response to a standardisation request and the reference of which has been published in the *Official Journal of the European Union*, or by other means as provided for in the relevant Union legislation;

(14) '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 standard development organisations, the European stakeholder organisations, national standardisation bodies, Member States, the Commission as well as stakeholders taking part in the standardisation process;

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

[24] 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).

(16) ‘standardisation request’ means a decision of the Commission addressed to a European standardisation organisation or a designated standard development organisation requesting to deliver or revise standards or standardisation deliverables to be referenced in support of Union legislation and policies;

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

(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 Organisation for Standardisation (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 for the development, adoption and use of standards and standardisation deliverables, in particular with the principles of openness, transparency, consensus 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 such as 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 standard development organisations shall make public on their website, for each requested standard and standardisation deliverable, the list of organisations and stakeholders that participate in its development or revision, together with the interests and objectives that these organisations and stakeholders represent.

Article 5

Access to referenced standards and standardisation deliverables

1. European standardisation organisations and designated standard development organisations shall provide unrestricted free online access to referenced standards and standardisation deliverables, including any amendments, corrigenda and referenced revisions thereof, in any official language that is authentic for such referenced standards and standardisation deliverables.

2. European standardisation organisations and designated standard development organisations shall ensure that referenced standards and standardisation deliverables are available in a readable, searchable, printable, [downloadable] 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* or in accordance with the relevant Union legislation.

3. European standardisation organisations and designated standard 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 standard 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.

2. European standardisation organisations and designated standard development organisations shall ensure the interoperability of the machine-readable formats of the requested standards and standardisation deliverables.

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 and common specifications;

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

   (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 standard development organisations shall make available to the Commission, through an IT system which is

interoperable with the EU Standards Platform, the relevant information on their standardisation activities under this Regulation.

Article 8

Objectives of Union financing of European standardisation

1. The Union and Member States shall contribute to the financial sustainability of the European standardisation system, in particular the activities of the European standardisation organisations and national standardisation bodies in support of Union legislation and policies.

2. Financial support from the Union budget may, in particular, be granted for any of the following standardisation objectives, in accordance with the rules of the relevant funding programmes:

(a) to ensure the development and revision of requested standards and standardisation deliverables;

(b) to ensure the quality, coherence and conformity of requested standards and standardisation deliverables with the corresponding Union legislation and policies;

(c) to strengthen the evidence based and strategic capacity of the European standardisation system through studies, evaluations, research and cooperation activities, including international cooperation;

(d) to promote the inclusiveness of the European standardisation system, notably the functioning of European stakeholder organisations and the participation of European experts in technical standardisation work;

(e) to support the functioning and governance of the European standardisation system, in particular of European standardisation organisations and national standardisation bodies;

(f) to enhance the accessibility and usability of requested standards and standardisation deliverables;

(g) to promote the interoperability of requested standards and standardisation deliverables;

(h) to promote the global relevance of the European standardisation system.

3. Financial support from the Union may, in particular, be granted to any of the following bodies, in accordance with the rules of the relevant Union funding programmes:

(a) European standardisation organisations;

(b) designated standard development organisations;

(c) European stakeholder organisations;

(d) national standardisation bodies.

4. The Commission shall monitor the financial sustainability of the European standardisation organisations and their ability to engage in standardisation activities in support of Union legislation and policies. 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 once per year, by the 31st of January each year.

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. The European standardisation organisations, European stakeholder organisations, Member States, designated standard development organisations, and industry, research and innovation stakeholders may provide their opinions 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 [Exercise of the Delegation] to amend Annex I to designate new European standardisation organisations or to withdraw a European standardisation organisation.

3. The Commission may only 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 is no longer able to comply with the requirements set out in this Regulation;

(b) based on the monitoring of the key performance indicators referred to in Article 13 [Key performance indicators and performance management of ESOs], it does not ensure 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

1. 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 that are needed for fulfilling a standardisation request;

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

2. European standardisation organisations shall allow for the participation of the Commission in their governance decision bodies and in their technical bodies.

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 application by European standardisation organisations of Articles 4 [Transparency of standard development], 5 [Access to referenced standards], 17 [Stakeholder participation in European standardisation] and 18 [European stakeholder organisations];

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

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

   (g) 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 an implementing act in accordance with the advisory procedure referred to in Article 40(2)[Committee procedure/advisory] 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. The European standardisation organisations shall send an annual report on the implementation of this Regulation to the Commission, by the 31st of January each year, covering the preceding calendar year. In that report they shall provide details of the key performance indicators established in accordance with paragraph 2. The European standardisation organisations shall publish a non-confidential version of the report on their 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 and implementation of standardisation requests.

2. The cooperation referred to in paragraph 1 shall be based on transparency, the timely exchange of information and appropriate consultation between the Commission and the European standardisation organisations and shall duly take into account the Union's legal and policy requirements.

3. The European standardisation organisations shall ensure the timely implementation of standardisation requests and delivery of standards and standardisation deliverables in accordance with the objectives and timeframes laid down by the Commission. The European standardisation organisations shall ensure the accuracy of their public information on the status of requested standards and standardisation deliverables.

4. The Commission and the European standardisation organisations may also cooperate to promote the development of European standards and European standardisation deliverables to support market developments or the Union's competitiveness and research and innovation policies, irrespective of whether a standardisation request was adopted.

5. The European standardisation organisations shall, without delay, notify the Commission of any amendment, renewal, suspension or termination of any cooperation agreement or similar arrangement with other standard development organisations, where this may affect the implementation of this Regulation.

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 national standardisation body shall establish 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 or amend, is developing or amending, or has adopted within the period of the preceding work programme, unless those standards or standardisation deliverables are transpositions of European standards or European standardisation deliverables.

2. The work programme shall indicate, in respect of each standard and standardisation deliverable:

   (a) the subject matter;

   (b) the stage attained in the development of the standards and standardisation deliverables;

   (c) the Union legislation or policies which the standards and standardisation deliverables support, where relevant;

   (d) the references of any international standards on which the standards and standardisation deliverables are based.

3. Each European standardisation organisation and 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 notify the publication of its work programme without delay to the other European standardisation organisations, the national standardisation bodies and the Commission.

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

6. During the development of requested standards and standardisation deliverables, national standardisation bodies shall not take any action which could prejudice the harmonisation intended and, in particular, shall not publish new or revised 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 at least, 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 be involved passively or actively, by sending an observer, in the planned activities.

5. After the Commission has published, in accordance with Article 25(3) [Assessment of ESO standards], the reference of a standard, national standardisation bodies shall withdraw or revise all conflicting national standards within a reasonable timeframe and shall not publish any new or revised 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, and other relevant stakeholders, such as open-source organisations, and shall promote 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 for a maximum period of four years 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 an implementing act following an open, non-discriminatory and transparent process.

2. The European stakeholder organisations designated in accordance with paragraph 1 shall participate in standardisation activities 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 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 and adoption 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. This report shall contain, in particular, detailed information about their membership and the activities undertaken pursuant to paragraphs 2 and 3.

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 shall 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 participation in their technical bodies, [and provide them with the necessary access to such standards and standardisation deliverables, as well as preparatory and explanatory documents, in a searchable, printable, downloadable and electronically accessible format on a cost-basis].

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. For the purposes of paragraph 1, national standardisation bodies shall ensure all the following:

   (a) to identify, in their annual work programmes, the standardisation projects, which are of particular interests to the stakeholders referred to in paragraph 1;

   (b) to grant the stakeholders referred to in paragraph 1 access to standardisation activities, without obliging them to become members of a national standardisation body;

   (c) to grant the stakeholders referred to in paragraph 1 free access to participate in their standardisation activities, or allow for such participation under special rates;

   (d) to grant the stakeholders referred to in paragraph 1 free access to draft standards and standardisation deliverables;

   (e) to apply reduced rates to the stakeholders referred to in paragraph 1 for the provision of standards 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 or revision 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 inclusiveness of stakeholder participation and consensus that may reasonably be achieved;

   (e) the relevance, quality and market uptake of existing technical specifications or standards developed by other standard development organisations;

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

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

3. The 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 [Standardisation request to ESO];

   (b) issue a standardisation request to one or more designated standard development organisations in accordance with Article 29 [Standardisation request to designated SDOs];

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

Article 23

Standardisation requests to European standardisation organisations

1. The Commission may address a standardisation request to one or more European standardisation organisations to deliver European standards or European standardisation deliverables, and, where appropriate, their revisions.

2. The Commission shall endeavour to adopt the standardisation request by means of an implementing act within 12 months from the date of receipt of the response to the consultation referred to in Article 22(3)[Consultation of ESOs].

3. The Commission shall determine in the standardisation request the requirements regarding the content to be met by the requested standards or standardisation deliverables, a deadline for their delivery and, where appropriate, requirements regarding the process for developing the requested standards or standardisation deliverables. The standardisation request shall have a set date of expiry.

4. 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) set specific requirements for the participation of targeted stakeholders in the standardisation process;

(d) oblige the European standardisation organisations to take into account identified existing technical specifications or standards from other standard development organisations;

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

(f) 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 to entities in third countries that effectively meet the interests of the Union;

(g) set specific requirements for the cooperation between European standardisation organisations and international standardisation bodies, related to the exception referred to in Article 35(2) [International first principle and cooperation with international standardisation bodies];

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

5. Before adopting a standardisation request, the Commission shall publish the draft standardisation request on the EU Standards Platform, except in justified cases. The European standardisation organisations, the European stakeholder organisations and

sectoral experts may provide their opinions within one month following the publication of the draft standardisation request.

6. Following the publication referred to in paragraph 5 of this Article, the Commission shall endeavour to adopt the standardisation request within three months from the end of the consultation referred to in paragraph 5 of this Article. Where the standardisation request specifies requirements referred to in paragraph 4, points (e) to (g), of this Article, the Commission shall adopt the standardisation request by means of an implementing act, in accordance with the examination procedure referred to in Article 40(3) [Committee procedure/examination] within six months from the end of the consultation referred to in paragraph 5 of this Article.

7. The relevant European standardisation organisations shall indicate whether they accept the standardisation request within 20 working days 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 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 the activities they undertook and the progress they 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 as circulated for public comments or scrutiny and relevant normative references, and upon request any adopted documents drafted in response to a standardisation request. They shall take due account of the Commission's comments on those draft documents to promote compliance with the standardisation request in view of the assessment by the Commission referred to in Article 25(2) [Assessment of ESO standards].

3. The Commission may amend a standardisation request as regards the deadlines for the delivery of requested standards or standardisation deliverables or the expiry date set out in the standardisation request or the clarification of the requirements to be met without the procedure laid down in Article 23(5) [Standardisation request ESO].

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 according to their internal procedures 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, with the objectives of the relevant Union policies, the Commission shall publish its reference in the *Official Journal of the European Union* by means of an implementing act, 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, or where appropriate, the objectives of the relevant Union policies, the Commission may publish its reference with restrictions in the *Official Journal of the European Union* by means of an implementing act, 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 amending or revising a referenced standard or standardisation deliverable. In case the standardisation request has not expired at the moment of adoption of the amended or revised standard or standardisation deliverable, the Commission shall publish the reference to that standard or standardisation deliverable in the *Official Journal of the European Union* by means of an implementing act, or by other means as provided for in the relevant Union legislation, 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, or 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 23(3) [Standardisation request to ESO], point (b), not to have been appropriately taken, the Commission 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 standard development organisations in accordance with Article 29 [Standardisation request to SDOs];

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

Chapter 4
Other standardisation processes and safeguard mechanisms

SECTION 1
STANDARDISATION REQUESTS TO DESIGNATED STANDARD DEVELOPMENT ORGANISATIONS

Article 26

Designation of standard development organisations

1. The Commission may, by means of an implementing act adopted in accordance with the examination procedure referred to in Article 40(3) [Committee procedures/examination], designate a standard development organisation which may be requested to develop standards and standardisation deliverables in accordance with Article 29 [Standardisation request to SDOs].

2. The Commission may only designate, in accordance with paragraph 1 of this Article, a standard 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 [Requirements for SDOs]. The Commission may simultaneously designate a standard development organisation in accordance with paragraph 1 of this Article and address it a standardisation request in accordance with Article 29 [Standardisation request to SDOs].

3. The Commission may, by means of an implementing act adopted in accordance with the examination procedure referred to in Article 40(3) [Committee procedures], withdraw the designation referred to in paragraphs 1 and 3 of this Article where the standard development organisation no longer complies with the requirements laid down in Article 27 [Requirements for SDOs] or is otherwise no longer able to effectively serve the interests of the Union.

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

Article 27

Requirements for the designated standard development organisations

1. Standard development organisations designated in accordance with Article 26 [Designation of SDOs] shall meet all of the following requirements:

(a) not be an international standardisation body, a national standardisation body or a national 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 standard development organisations shall ensure all of the following:

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

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

(c) the transparency of their work programme.

3. When developing standards and standardisation deliverables requested in accordance with Article 29 [Standardisation requests to SDOs], designated standard development organisations shall ensure all of the following:

(a) 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 [European stakeholder organisations];

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

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

Article 28

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

1. Each designated standard development organisation shall send, at least 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 interoperability and coherence of the draft requested standards and standardisation deliverables with their referenced standards and standardisation deliverables, to designated standard development organisations within one month from the date of receipt of the draft requested standards or standardisation deliverables.

2. Each designated standard 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.

3. When a designated standard development organisation receives comments indicating that the draft requested standards or standardisation deliverables would have a negative impact on the internal market, it shall consult the Commission before adopting it.

Article 29

Standardisation requests to designated standard development organisations

1. The Commission may address a standardisation request to one or more designated standard development organisations to deliver standards or standardisation deliverables, and, where appropriate, their revisions, in any of the following cases:

(a) the European standardisation organisations consulted in accordance with Article 22 [Consultation of ESOs] 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 [Consultation of ESOs], the response given to the points referred to in paragraph 2 of that Article is not satisfactory;

(c) none of the European standardisation organisations to which the Commission addressed a request in accordance with Article 23 [Standardisation request to ESOs] 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 [Standardisation request to ESO];

(e) the Commission deems that the steps referred to in Article 23(3) [Standardisation request to ESO] point (b) have not been appropriately taken;

(f) the Commission has deemed that the requested standards or standardisation deliverables are non-compliant in accordance with Article 25(5) [Assessment standards ESO].

2. The Commission shall determine in the standardisation request the requirements regarding the content to be met by the requested standards or standardisation deliverables, a deadline for their delivery and, where appropriate, requirements regarding the process for developing the requested standards or standardisation deliverables. The standardisation request shall have 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) set specific requirements for the participation of targeted stakeholders in the standardisation process;

(d) oblige the designated standard development organisations to take into account identified existing technical specifications or standards from other standard development organisations;

(e) 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 to entities in third countries that effectively meet the interests of the Union;

(f) set specific requirements for the cooperation between designated standard development organisations and international standardisation bodies, related to the exception referred to in Article 35(2) [International first principle and cooperation with international standardisation bodies];

(g) 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. The designated standard development organisations, the European stakeholder organisations, European standardisation organisations and sectoral experts may provide their opinions within one month following the publication of the draft standardisation request.

5. Following the publication referred to in paragraph 4 of this Article, the Commission shall endeavour to adopt the standardisation request within six months from the end of the consultation referred to in paragraph 4 of this Article, by means of an implementing act adopted in accordance with the examination procedure referred to in Article 40(3) [Committee procedure].

6. The relevant designated standard development organisations shall indicate whether they accept the standardisation request within 20 working days 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 standard development organisations have accepted it.

Article 30

Implementation of standardisation requests addressed to designated standard development organisations

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

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

3. The Commission may amend a standardisation request as regards the deadlines for the delivery of requested standards or standardisation deliverables or the expiry date set out in the standardisation request or the clarification of the requirements to be met without the procedure laid down in Article 29(4) [Standardisation request SDOs].

Article 31

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

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

2. The Commission shall assess, with the support of relevant European sectoral experts and of the designated standard development organisations responsible for their development, 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 level of interoperability 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 interoperable and coherent with other relevant referenced standards and standardisation deliverables, the Commission shall publish its reference in the *Official Journal of the European Union* by means of an implementing act, 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, or, where appropriate, the objectives of the relevant Union policies, the Commission may publish its reference with restrictions in the *Official Journal of the European Union* by means of an implementing act, 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, or does not appropriately comply with the standardisation request, or is not interoperable or coherent with the relevant referenced standards and standardisation deliverables, the Commission shall inform the relevant designated standard 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 standard development organisations shall notify the Commission without delay when they engage in the process of amending or revising a referenced standard or standardisation deliverable. In case the standardisation request has not expired at the moment of adoption of the amended or revised standard or standardisation deliverable, the Commission shall publish the reference to that standard or standardisation deliverable in the *Official Journal of the European Union* by means of an implementing act, or by other means as provided for in the relevant Union legislation, 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 interoperable and 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, or 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) [Standardisation request to SDOs], point (b), not to have been appropriately taken, the Commission may take any of the following decisions:

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

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

SECTION 2
COMMON SPECIFICATIONS AND SAFEGUARD MECHANISMS

Article 32

Common specifications

1. The Commission may adopt an implementing act 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 [Consultation of ESOs] have not replied or have informed the Commission that they do not intend to accept the standardisation request regarding the standards or standardisation deliverables; or

(b) the Commission deems that, following the consultation under Article 22 [Consultation of ESOs], the response given to the points referred to in paragraph 2 of that Article is not satisfactory.

3. Without prejudice to the application of relevant Union legislation, the Commission may also adopt the implementing act referred to in paragraph 1 of this Article, where it has adopted, in accordance with Article 23 [Standardisation request to ESOs] or 29 [Standardisation request to SDOs], a standardisation request covering the requirements referred to in paragraph 1 of this Article, 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 published within a reasonable period, and where any of the following conditions is met:

(a) none of the European standardisation organisations or designated standard development organisations to which the Commission addressed a request in accordance with Article 23 [Standardisation request to ESOs] or 29 [Standardisation request to SDOs] respectively have 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) [Standardisation request to ESO], point (b), or 29(3) [Standardisation request to SDO], 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) [Assessment standards ESOs] or 31(5) [Assessment standards SDOs];

(e) the Commission deems that the harmonised standard, or parts thereof, does not entirely satisfy the requirements set out in the relevant Union legislation pursuant to the procedure set out in Article 33 [Safeguard notification procedure].

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 by the Committee set out in the corresponding Union legislation or, in the absence of such a Committee, by the Committee set out in Article 40 [Committee procedure] in accordance with the procedure referred to in Article 40(3).

5. Before drafting the implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 40 [Committee procedure] whether it considers that the requirements referred to in paragraph 2 or 3 of this Article are met.

6. Before drafting the 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 consult relevant stakeholders. The Commission may use, where relevant, the documents referred to in Article 24(2) [Implementation of Standardisation request to ESOs] or 30(2) [Implementation of Standardisation request to SDOs] 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 is delivered to the Commission for the purpose of publishing its reference in the *Official Journal of the European Union*, the Commission shall assess that standard in accordance with Article 25 [Assessment ESO] or 31 [Assessment SDO].

9. Where the reference of the standard referred to in paragraph 8 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 procedure

1. Where a Member State or the European Parliament considers that a referenced standard or standardisation deliverable or parts thereof, or common specification or parts thereof, do not entirely satisfy the requirements set out in the relevant Union legislation which they aim to cover, it shall immediately notify the Commission, the other Member States and the European Parliament, and submit 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*, or by other means as provided for in the relevant Union legislation, by means of an implementing act, 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*, or by other means as provided for in the relevant Union legislation, by means of an implementing act, or to maintain, amend or repeal the common specification.

4. [The Commission shall consult the committee set up by the corresponding Union legislation, if it exists, or the committee set up in Article 40 [Committee procedures], before adopting a decision pursuant to paragraph 2 or 3 of this Article amending or repealing a common specification.]

Article 34

Withdrawal of referenced standards and standardisation deliverables

1. The European standardisation organisations and designated standard 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*, or by other means as provided for in the relevant Union legislation.

2. The Commission may withdraw a referenced standard or standardisation deliverable from the *Official Journal of the European Union*, or by other means as provided for in the relevant Union legislation, if the Commission deems that the referenced standard or standardisation deliverable no longer represents the state of the art or no longer satisfies the requirements set out in the corresponding Union legislation which it aimed to cover.

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, European standardisation organisations and designated standard development organisations shall use them, or the relevant parts thereof, as a basis for the requested standards and standardisation deliverables they develop, except where such international standards or relevant parts thereof would be an ineffective or inappropriate means for the legitimate objectives pursued. European

standardisation organisations and designated standard development organisations shall inform the Commission accordingly.

2. If the Commission considers that an international standard or relevant parts thereof are ineffective or inappropriate for the legitimate objective pursued, the Commission may specify in the standardisation request in accordance with Article 23(4), point (g) [Standardisation request to ESO] or 29(3) point (f) [Standardisation request to SDOs] whether an exception to paragraph 1 of this Article is warranted and request European standardisation organisations or designated standard development organisations not to use an existing international standard or international standard under development, or the relevant parts thereof.

Article 36

European coordination on international standardisation

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

2. Member States and European standardisation organisations shall regularly inform the Commission about relevant developments in international standardisation bodies.

Article 37

Cooperation with other standard development organisations

1. European standardisation organisations and designated standard development organisations shall inform the Commission if they decide to enter into an agreement with a standard development organisation which may affect their standardisation activities undertaken in support of Union legislation and policies.

2. European standardisation organisations and designated standard development organisations shall promote the standards and the standardisation deliverables developed upon request of the Commission when they participate in the work of other standard development organisations.

Chapter 6
Governance, delegated powers and committee procedures

Article 38

Chief Standardisation Officer and Centre of Excellence on European Standardisation

1. The Commission shall appoint a Chief Standardisation Officer.

2. The Chief Standardisation Officer shall coordinate the standardisation activities of the Commission and the relationship with European standardisation organisations and designated standard development organisations to ensure public expertise, technical and strategic support to European standardisation, alignment between European standardisation and Union policies and a Union approach to international standardisation.

3. The Chief Standardisation Officer shall be supported by a Centre of Excellence on European Standardisation within the Commission.

4. The Centre referred to in paragraph 3 of this Article 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 standard 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 [Requirements for SDOs];

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

(h) coordinate the development of pre-normative specifications in areas of public relevance and support and 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) and (4) [European standardisation organisations] shall be conferred on the Commission for a period of five years from *(OP: Inset date of entry into force of this Regulation)*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 10(2) and (4)[European standardisation organisations] 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 act adopted pursuant to Article 10(2) and (4) [European standardisation organisations] 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 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

Committee cooperation with standardisation organisations and stakeholders

The committee referred to in Article 40 [Committee procedure] shall work in cooperation with the European standardisation organisations, the European stakeholder organisations and, where appropriate, with designated standard development organisations. The Commission shall regularly inform the committee referred to in Article 40 [Committee procedure] on the implementation of this Regulation.

Article 42

Evaluation and review

1. By *(OP: insert date of entry into force of this Regulation + three 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 evaluate the impact of the procedure set out in Articles 23, 24 and 25 and 29, 30 and 31 on the average time needed for obtaining referenced standards and standardisation deliverables in support of Union legislation and policies. The Commission shall present its conclusions in a report to the European Parliament and to the Council. Where appropriate, that report shall be accompanied by a legislative proposal to amend this Regulation.

Chapter 7
Final provisions

Article 43

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.

2. [Decisions 2014/188/EU, 2014/771/EU, (EU) 2015/1302, (EU) 2016/120, (EU) 2016/1765, (EU) 2017/168, (EU) 2017/1358 and (EU) 2017/2288 are repealed.]

Article 44

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 Brussels,

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

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

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.

<u>Specific objective No 1</u>

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 standard 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 %.

<u>Specific objective No 2</u>

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 as part of the European Product Package, supporting EU competitiveness, technological sovereignty, interoperability, legal certainty and the implementation of Union legislation and policies.

The initiative should be implemented together with the European Product Act as part of the European Product Package, which it complements by ensuring that legislation falling under the scope of the European Product Act can effectively rely on the standards required for their effective and timely implementation.

The initiative should enter into force in 2028 and should be complemented by targeted changes to relevant sectoral legislation to align them to the general framework introduced by the European Product Package.

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

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

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 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. The future Single Market and Customs Programme under the 2028–2034 framework will continue to support the effective functioning of the internal market through standardisation processes and will be the main EU financial instrument supporting the European standardisation system. The European Competitiveness Fund and the Horizon Europe programme will also contribute to the efficiency of the European standardisation system by contributing to the financing of strategic standardisation activities for the Union.

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, are planned to 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.

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;

(2) Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://eceuropaeu.sharepoint.com/sites/budgpedia/SitePages/management-modes-and-bodies.aspx.

- ☐ 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 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 EISMEA.

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 will also be implemented through direct management using the financial mechanisms of the upcoming Single Market and Customs Programme.

Funding will continue to be provided through operating grants to European standardisation organisations and European stakeholder organisations. Tasks may be implemented by the Commission or by 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

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.

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

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. (3)	from EFTA countries (4)	from candidate countries and potential candidates (5)	from other third countries	other assigned revenue
2	05.03.01.01 - Internal market, implementation tools, market surveillanc	Diff.	NO	NO	NO	NO

(3) Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
(4) EFTA: European Free Trade Association.
(5) Candidate countries and, where applicable, potential candidates from the Western Balkans.

	e and European standardisation					
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

New budget lines requested

<u>In order</u> 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
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.Y	Diff./Non-	YES/NO	YES/NO	YES/NO	YES/NO

	Y.YY]	diff.				

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:

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 05.030101 - Internal market, implementation tools, market surveillance and European standardisation	Commitments	(1a)	23,714	23,714	23,714	23,714	23,714	23,714	23,714	**165,998**
	Payments	(2a)	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	**p.m.**
Budget line	Commitments	(1b)								**0**
	Payments	(2b)								**0**

Appropriations of an administrative nature financed from the envelope of specific programmes [6]										
Administrative support line of SMCP		(3)	0	0,213	0,213	0,213	0,213	0,213	0,213	**1,278**
TOTAL appropriations for DG GROW	Commitments	=1a+1b+3	**23,714**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**167,276**
	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	23,714	23,714	23,714	23,714	23,714	23,714	**165,998**
	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**	**167,276**
	Payments	=5+6	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**p.m.**

(6) 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.

			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	23,714	23,714	23,714	23,714	23,714	23,714	**165,998**
	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 Headings 1 to 3 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**23,714**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**23,927**	**167,276**
	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' [7]

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**

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

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**

TOTAL appropria	(Total commitme	8,710	9,777	9,777	9,777	9,777	9,777	9,777	67,369

tions under HEADING 4 of the mult	nts = Total payments)								

iannual financial framework									

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 of the multiannual financial framework	Commitments	**32,424**	**33,704**	**33,704**	**33,704**	**33,704**	**33,704**	**33,704**	**234,645**
	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 Section 1.6)						**TOTAL**	
	OUTPUTS																	
	Type (8)	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total Cost
SPECIFIC OBJECTIVE No 1 (9): [...]																		
Output																		
Output																		

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

(9) As described in point 1.4.2. 'Specific objective(s)...'

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 MFF 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	0	0	0	0	0	0	**0**
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	0	0	0	0	0	0	**0**
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**

3.2.3.3. Total appropriations

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 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	0	0	0	0	0	0	**0**
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	0	0	0	0	0	0	**0**
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) [(10)]

VOTED APPROPRIATIONS	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**
Establishment plan posts (officials and temporary staff)							
20 01 02 01 (Headquarters and Commission's Representation Offices)	43	48,5	48,5	48,5	48,5	48,5	48,5

(10) 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.

20 01 02 03 (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
Other budget lines (specify)		0	0	0	0	0	0	0
External staff (in FTEs)								
20 02 01 (AC, END from the 'global envelope')		3,5	3,5	3,5	3,5	3,5	3,5	3,5
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0	0	0	0
Admin. Support line [XX.01.YY.YY]	at Headquarters	0	0	0	0	0	0	0
	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	2	2	2	2	2	2
TOTAL		**46,5**	**54**	**54**	**54**	**54**	**54**	**54**

3.2.4.3. 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 standard development organisations and the integration of specifications from other standard 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 will 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 shall 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 standard development organisations and the integration of specifications from other standard 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).

☐ 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 **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	Total
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 [11]						
		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**

[11] 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.

Article								

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

[...]

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 standard 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 implementation, and provide information on the performance of the European standardisation system. European standardisation organisations and designated standard 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 made available by European standardisation organisations and designated standard	

			development organisations shall be provided in a timely, structured and machine-readable manner and shall include, where appropriate, metadata, identifiers and status information necessary to ensure the traceability, consistency and reliability of the information displayed or processed through the EU Standards Platform.	
Requirement 2	Article 6(1): European standardisation organisations and designated standard 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 standard development organisations	European standardisation organisations and standard development organisations should ensure that the requested standard are available in electronic form and machine-readable format, with the metadata necessary to ensure their identification, traceability and use.	

Requirement 3	Article 6(2): European standardisation organisations and designated standard development organisations shall ensure that the machine-readable format of requested standards and standardisation deliverables are interoperable.	European standardisation organisations and designated standard development organisations	European standardisation organisations and designated standard development organisations shall ensure that the machine-readable format of requested standards and standardisation deliverables are interoperable, suitable for digital exchange and automated processing.	

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,	Requirement 1	Technical specifications require open, interoperable metadata schemas (XML/JSON), API-based interfaces, and alignment with European Interoperability Framework (EIF) and Interoperable

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).		Europe solutions.
Digital production outputs and machine-readable standards and standardisation deliverables by European standardisation organisations and standard development organisations.	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 standard 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 standard 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 deliverables: title, reference number, version, status, adoption/publication/withdrawal dates, responsible organisations, links to relevant Union acts or policy areas, access	Requirement 1	European Commission, European standardisation organisations and designated standard development organisations	European Commission	Adoption, amendment, withdrawal of standardisation requests; development, adoption, revision of standards; and periodic performance reporting	Event-driven for changes (near real-time) and performance data, with periodic consolidation of performance data (quarterly/annually)

conditions/format, lifecycle data for standardisation requests/deliverables, and performance indicators (e.g. timeliness, responsiveness, uptake).					

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	European Commission		Building on current eNorm project.	

		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 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 standard development organisations.				

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

<u>Digital solution #1</u>

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)(NOT APPLICABLE)**	**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		The EU Standards Platform will require interactions between the Commission, European standardisation organisations and designated standard development organisations. The EU Standards Platform will use standard interoperable architectures (see: Interoperability Architecture Solutions | Interoperable Europe Portal) if possible/practical. 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.
Category of digital public services according to COFOG[12] #1				

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 sectorial policies. Please list the applicable digital and sectorial policies identified	Digital or sectorial policy #1 Digital or sectorial policy #2 Digital or sectorial policy #3	Barrier #1 Barrier #2 *Barrier #3*
Organisational measures for a smooth cross-border digital public services delivery. Please list the governance	Governance measure #1 Governance measure #2 *Governance measure #3*	Barrier #1 Barrier #2 *Barrier #3*

(12) https://op.europa.eu/en/web/eu-vocabularies/concept-scheme/-/resource?uri=http://data.europa.eu/7yx/cofog

measures foreseen		
Measures taken to ensure a shared understanding of the data. Please list such measures	Measure #1 Measure #2 *Measure #3*	Barrier #1 Barrier #2 *Barrier #3*
Use of commonly agreed open technical specifications and standards. Please list such measures	Measure #1 Measure #2 *Measure #3*	Barrier #1 Barrier #2 *Barrier #3*

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 EU standard platform should be operational at the latest at the date of entry into force of the Regulation, planned for 2028.

Annex I

European standardisation organisations

1. CEN – European Committee for Standardisation
2. CENELEC – European Committee for Electrotechnical Standardisation
3. ETSI – European Telecommunications Standards Institute

Annex II

Criteria for selecting European stakeholder organisations

1. A European organisation representing SMEs in European standardisation activities, shall:

   (a) be a non-governmental and non-profit-making body;

   (b) have as its statutory objectives and activities to represent the interests of SMEs in the standardisation process at European level, to raise their awareness for standardisation and conduct capacity-building initiatives, to motivate them to become involved in the standardisation process and to ensure their participation in technical committees;

   (c) have been mandated by non-profit organisations representing SMEs in at least two thirds of the Member States, to represent the interests of SMEs in the standardisation process at European level.

2. A European organisation representing consumers in European standardisation activities shall:

   (a) be a non-governmental, non-profit-making body, independent of industry, commercial and business or other conflicting interests;

   (b) have as its statutory objectives and activities to represent consumer interests in the standardisation process at European level;

   (c) have been mandated by national non-profit consumer organisations in at least two thirds of the Member States, to represent the interests of consumers in the standardisation process at European level.

3. A European organisation representing environmental interests in European standardisation activities shall:

   (a) be a non-governmental, non-profit-making body, independent of industry, commercial and business or other conflicting interests and working actively for environmental sustainability;

   (b) have as their statutory objectives and activities to represent environmental interests in the standardisation process at European level;

   (c) have been mandated by national non-profit environmental organisations in at least two thirds of the Member States, to represent environmental interests in the standardisation process at European level.

4. A European organisation representing social interests in European standardisation activities shall:

   (a) be a non-governmental, non-profit-making body, independent of industry, commercial and business or other conflicting interests;

   (b) have as its statutory objectives and activities to represent social interests in the standardisation process at European level;

   (c) have been mandated by national non-profit social organisations in at least two thirds of the Member States, to represent social interests in the standardisation process at European level.

Annex III

Correlation table

Regulation (EU) No 1025/2012	**This Regulation**
Article 1	Article 1
Article 2	Article 2
Article 3	Article 15
Article 4	Articles 16 and 28
Article 5(1)	Articles 17(1) and 18(3)
Article 5(2)	Article 17(2)
Article 6	Article 20
Article 7	Article 21
Article 8	Article 9
Article 9	Article 19
Article 10	Articles 23 to 25 and 29 to 31
Article 10(2)(a)	Article 12
Article 11	Article 33
Article 12	Article 7
Article 13	
Article 14	
Article 15	Article 8
Article 16	Article 8
Article 17	
Article 18	
Article 19	
Article 20	Article 39
Article 21	Article 39
Article 22	Article 40

Regulation (EU) No 1025/2012	**This Regulation**
Article 23	Article 41
Article 24(1)	Article 13(4)
Article 24(2)	Article 18(8)
Article 24(3)	Article 42(1)
Article 25	Article 42(2)
Article 26	
Article 27	Article 11
Article 28	
Article 29	Article 43
Article 30	Article 44
ANNEX I	ANNEX I
ANNEX II	
ANNEX III	ANNEX II
ANNEX IV	ANNEX III