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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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

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1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The legal basis for this proposal is Article 114 of the Treaty on the Functioning of the European Union ('TFEU') 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.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
Pursuant to Article 4(2)(a) TFEU, competence is shared between the Union and the Member States as this proposal concerns the functioning of the internal market.
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
- The Commission organised a wide consultation of stakeholders before proposing the act: it conducted a call for evidence, an open public consultation as well as targeted surveys, workshops, in-depth interviews, and bilateral meetings. The Commission also frequently consulted the High-Level Forum on European standardisation. All stakeholders concerned took part to the consultations, in particular: Member States, European standardisation organisations, national standardisation bodies, standards development organisation, businesses, representatives of civil society (European stakeholder organisations active in standardisation activities), research and innovation stakeholders and individual citizens. - The explanatory memorandum and the Impact Assessment accompanying the proposal both contain a section on the principle of subsidiarity (see answer to question 2.2 below).
2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?
The explanatory memorandum and Chapter 3 of the Impact Assessment accompanying this proposal provide a justification of the conformity of the proposal with the principle of subsidiarity.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

The objectives of the proposal, in particular to set up a harmonised framework for European standardisation, 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 the development of standards and concerns regarding financial sustainability, are shared across 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 is better suited to achieve the objectives of the proposal for the following reasons:

- The proposal will improve the functioning of the 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.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The objectives of the proposed action cannot be sufficiently achieved by Member States acting alone. The identified problems are common to all Member States, differentiated initiatives by Member States alone would be detrimental to the internal market and could negatively affect other Member States. This Regulation aims to create a harmonised framework facilitating the 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.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The problems identified in the Impact Assessment that the proposal aims to tackle all have a transnational dimension. Harmonised standards play a major role for the internal market, guaranteeing the interoperability, placing on the market and safety of products and services across the internal market, further facilitating a level playing field across the Union. The lengthy and complex standardisation process of European standardisation affects and stems from national standardisation systems as the European standardisation system is built on the cooperation between national standardisation bodies. The insufficient stakeholder participation in standardisation has a cross-border dimension as national standardisation systems need to be open to stakeholders from other Member States. The obligation to provide free access to harmonised standards following the case law of the Court of Justice of the European Union affects all national standardisation bodies that sell these harmonised standards, including across borders, as access needs to be guaranteed to an equal degree

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across the Union in each Member State. The diminishing global position of the Union and its Member States in international standardisation has a transnational dimension as each national standardisation body of a Member State is an independent member of international standardisation bodies.
(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[2] or significantly damage the interests of other Member States?
National action or the absence of the EU level action would significantly damage the interests of other Member States. The proposal aims at improving the functioning of the internal market by creating a harmonised framework for European standardisation, thereby facilitating exchange of goods and services, fostering interoperability, contributing to quality and consumer trust, and supporting technological development and the uptake of market innovation. Any initiative at the level of Member States might go against the objective of harmonisation, create technical barriers to trade for business within the internal market or diminish the influence and participation of other Member States in European and international standardisation.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
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 European standardisation system that fosters the same standards across the Union, with the same transparency in development and balanced participation of stakeholders. National action to address specific objectives of the proposal, for instance as regards improving inclusiveness or international influence, could also create an unlevel playing field within the Union.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The problems identified in the Impact Assessment are a common challenge across the Union and Member States, albeit to varying degrees. National standardisation systems all face similar challenges: lack of responsiveness, lack of balanced stakeholder participation, possibility of loss of revenues stemming from the free access to harmonised standards and declining influence at international level. The initiative has no differentiated impact at regional and local levels as standardisation is only conducted at national and European levels.
(e) Is the problem widespread across the EU or limited to a few Member States?
The problems are widespread across the EU and affect all Member States, albeit to a different extent, based on their industrial base and national standardisation systems.
(f) Are Member States overstretched in achieving the objectives of the planned measure?

[2] https://europa.eu/european-union/about-eu/eu-in-brief_en

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The proposal foresees targeted requirements on Member States to improve the functioning of their national standardisation bodies, in particular their ability to ensure an inclusive standardisation process at national level, and to share information on their participation in international standardisation activities.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

There is broad convergence of views, as expressed in the open public consultation to this proposal, that EU action is needed to achieve the objectives of the proposal and to improve the functioning of the European standardisation system. Stakeholders expressed strong support for targeted improvements to the existing European standardisation system, based on the existing horizontal framework created by Regulation (EU) No 1025/2012.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

The objectives of the proposed action can be achieved better at Union level, in particular to improve the functioning of the internal market and to foster the competitiveness of the Union. Standardisation eliminates technical barriers, enabling the free movement of goods and services and reducing costs for cross-border operators. A legally and financially sustainable European standardisation system is critical to effectively implement Union legislation and for the EU's ability to shape global standards in emerging technologies. EU-level action ensures policy coherence, supporting key priorities such as competitiveness and strategic autonomy, while avoiding the fragmentation that would result from divergent national approaches. Collective action leverages economies of scale in standardisation across Member States, mutualising standardisation costs and creating synergies, and enhances the EU's influence in international standardisation fora, which would not be achievable through the individual efforts of Member States.

(a) Are there clear benefits from EU level action?

There are clear benefits stemming from EU level action by improving an existing horizontal framework which is key to the functioning of the internal market, by addressing problems that are common to all Member States and creating synergies across Member States in fostering participation of stakeholders in standardisation at all levels – national, European and international which benefits the entire Union.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

The proposal will create economies of scale for businesses by reducing their compliance costs by making harmonised standards and standards in support of Union legislation and policies available earlier. This will improve the functioning of the internal market by fostering the convergence of technical solutions implemented by businesses to comply with Union legislation and access the internal market, while decreasing overall compliance costs for businesses. The Impact Assessment accompanying this proposal estimates these savings at EUR 295 million per year.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

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This proposal will not replace national policies as this proposal builds on the existing European framework for standardisation, Regulation (EU) No 1025/2012. The proposal does not create new national obligations but amends existing obligations at national level for national standardisation bodies. However, the proposal clarifies the Member States' responsibility to ensure the compliance of their national standardisation bodies with the Regulation.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposal does not lead to the loss of competences of Member States. It builds on the current European standardisation system, which has delivered benefits outweighing the loss of competence of the Member States. By identifying standards at European level to support Union legislation, this Regulation supports the harmonisation of the internal market and the competitiveness of the Union, while promoting active national standardisation activities to support European standardisation. The proposal will further increase the benefits of the European standardisation system, by reducing compliance costs for businesses, increasing trade, and strengthening the Union's influence in international standardisation.

(e) Will there be improved legal clarity for those having to implement the legislation?

This proposal will improve legal clarity for the actors of the European standardisation system and for the users of standards and standardisation deliverables in support of Union legislation and policies. It will increase legal certainty for business as regards the legal value of standards and standardisation deliverables, clarify the legal status of standards and standardisation deliverables requested by the Commission as well as clarify obligations of European standardisation organisations, designated standardisation organisations and national standardisation bodies for the delivery of standards and standardisation deliverables in support of Union legislation and policies.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The proposed revision 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 standardisation organisations in targeted situations, where the European standardisation organisations would not be able to deliver high-quality standards in a timely manner.

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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. These requirements target measures at the national level where the barriers to participation to standardisation are the highest. The obligation 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.

Improving coordination of European stakeholders in international standardisation is necessary to consolidate the Union's influence in international standardisation and is achieved by introducing 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 practices, without going beyond what is necessary by preserving the international first principle, whereby European standards should first seek to align with international standards.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed action is an appropriate way to achieve the intended objectives as it introduces targeted changes to the current European standardisation system, which should benefit in the long-term all stakeholders concerned and can be financed through redeployments within the existing Union budget. The proposal limits itself to improving the European processes for obtaining standards and standardisation deliverables in support of Union legislation and to better coordinating the European stakeholders active in international standardisation. It implements a proportionate approach to inclusiveness and free access to harmonised standards whose costs would be borne by European standardisations organisations, national standardisation bodies, businesses, and the Union budget through redeployments.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposal is strictly limited to improving the responsiveness of the European standardisation system, which Member States cannot achieve on their own, to improving coordination across EU actors in international standardisation and to foster a balanced stakeholder participation in EU standardisation, which is better achieved at Union level in order to ensure there is no unlevel playing field in standardisation across Member States.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

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

designated standard development organisations, European stakeholder organisations, and the Commission.
(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)
The proposal mostly sets out requirements on the functioning of the European standardisation system and as such does not affect national decision-making. To support the objective of ensuring a balanced stakeholder participation in the European standardisation system, the proposal also sets requirements at national level for national standardisation bodies, to promote the level playing field in standardisation across the Union and to ensure a joint minimum level of inclusiveness. This is proportionate to the objective of the Regulation as not setting joint minimum requirements could undermine the European standardisation system if some national systems would be less inclusive and more prone to imbalanced stakeholder participation.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative does not create operational financial costs for the Union budget as new activities to support the viability of the European standardisation system will be financed through redeployment of existing Union budget. It creates limited additional costs for national standardisation bodies, estimated in the Impact Assessment at EUR 1.9 million per year. It would also create additional administrative costs for the Union in the form of additional human resources to support the effective implementation of the proposal that will be mostly covered through internal redeployment. Net additional administrative costs are estimated in the Legislative Financial and Digital statement at EUR 0.213 per year.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
The initiative has taken into account special circumstances applying in individual Member States, in particular the different level of dependency on the sales of harmonised standards by different national standardisation bodies. To take into account these special circumstances, the proposal foresees the possibilities for differentiated financial support to such national standardisation bodies, via the European standardisation organisations and within the possibility for redeployment of the Union budget.

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