



## Common Specifications

### Fallback or challenge for harmonised standards within the EU?

European harmonised standards have long been the primary tool businesses use to demonstrate compliance with EU product legislation, supporting innovation, legal certainty and competitiveness. However, delays in their availability have created challenges, leaving companies facing uncertainty and higher compliance costs. To address these gaps, several legislative acts have already introduced common specifications, and their use is now being proposed in others as an alternative instrument for demonstrating conformity.

This paper outlines the key processes and principles of the European Standardisation Regulation<sup>1</sup> that ensure harmonised standards are legitimate, inclusive and internationally aligned. It also examines the unclear procedures for drafting common specifications, their potential risks and the need for clear safeguards and conditions for their use so that they do not undermine the European standardisation system.

### Key processes and principles in developing European harmonised standards

The development of European harmonised standards follows processes that ensure legitimacy and technical robustness. The European Commission first consults stakeholders on a draft request, which, after revision and approval by Member States, becomes a formal mandate to the European Standardisation Organisations. Once a request is accepted, drafting takes place in technical committees comprising national delegations and stakeholders representing SMEs, consumers and social interests. This consensus-based process delivers standards that are broadly accepted and aligned with principles of transparency, openness and inclusiveness.

The system reflects the EU's commitments under the WTO Agreement on Technical Barriers to Trade, which requires that standard-setting to be transparent, inclusive and to build on international standards where relevant. The Vienna and Frankfurt Agreements reinforce this by enabling European adoption of standards from the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). By aligning European standards with international standards, the system facilitates global market access for EU products and supports the EU's active role in international standardisation.

<sup>1</sup> Regulation (EU) No 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 No 1673/2006/EC of the European Parliament and of the Council.

The Commission monitors the development stage to ensure that each standard remains consistent with the original mandate. Once adopted and approved, a reference is published in the Official Journal of the European Union, giving products a presumption of conformity with EU legislation and supporting legal certainty and market surveillance.

The European harmonisation system has recently come under pressure. Delays in harmonised standards, partly due to growing technological complexity, have made it more difficult for companies to demonstrate compliance. In their absence, businesses often face costly third-party assessments, adding uncertainty, slowing market access and weakening competitiveness. Stakeholders across industry have expressed concern, while the Commission has been seeking solutions. One response has been to introduce common specifications in several sectoral acts, intended to ensure the timely and effective application of EU product legislation.

## Common specifications as a fallback instrument

Common specifications thus represent the Commission's proposed fallback tool, intended to help businesses meet legal requirements in the absence of harmonised standards and to avoid costly third-party assessments. They are already foreseen in ten sectoral acts and are designed to fill gaps when harmonised standards are delayed or unavailable. Unlike harmonised standards, common specifications are adopted by the Commission through implementing acts.

While initially framed as a narrowly defined fallback, the Commission now appears more inclined to rely on common specifications. This shift has gained momentum in the wake of the Court of Justice of the European Union (CJEU) ruling on public access to harmonised standards<sup>2</sup> and is further driven by the absence of ISO/IEC-based standards, which the Commission's staff working document<sup>3</sup> notes are already undermining the Single Market. Since March 2024, no ISO/IEC-based harmonised standards have been provided for citation, while litigation between the international organisations and the Commission continues. Against this background, the Commission appears likely to make greater use of common specifications whenever harmonised standards are unavailable.

As part of the Omnibus IV package, the Commission proposes to extend common specifications to sixteen additional directives and regulations. However, the provisions on when they may be adopted are vaguely formulated, and the proposal does not explicitly require harmonised standards to be considered first, raising concerns that they could be used as a substitute rather than as a strictly limited fallback. Questions also arise regarding the preparatory phase. While harmonised standards involve consultation and approval before a request is issued, it is unclear whether any similar safeguards will apply to common specifications.

While the Commission presents common specifications as a fallback solution, they also raise significant challenges. Questions remain about how they will be developed, who will be involved and whether the process will reflect the openness, inclusiveness and consensus that characterise harmonised standards. Their relationship with international standards is also uncertain, although WTO rules require international standards to serve as the basis for technical regulations and conformity assessment. Careful coordination is

<sup>2</sup> Judgment of 5 March 2024, *Public.Resource.Org Inc. and Right to Know CLG v Commission and Others*, Case C-588/21 P.

<sup>3</sup> Commission staff working document Accompanying the documents 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 and Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 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) 503 final} - {COM(2025) 504 final}.

needed to ensure that common specifications remain consistent with European and international standardisation practices and do not, over time, undermine Europe's competitiveness.

Copyright rules creates an additional complication. If common specifications build on ISO/IEC texts, it is unclear whether they can be made freely accessible. The issue has become increasingly pressing since such standards have not been transmitted to the Commission due to copyright restrictions. Without a new framework, common specifications risk either excluding international standards and thus weakening global alignment, or reproducing them without compensation, creating legal disputes and straining cooperation. The copyright issue is still unresolved and must be addressed to ensure that common specifications are both accessible and internationally compatible.

Another aspect is timing, particularly regarding the planned extension of common specifications to additional legislative acts. A revision of the Standardisation Regulation is scheduled for 2026 to make the system faster, more inclusive and more flexible. According to the Commission, this reform will not address the immediate difficulties currently facing the system. Common specifications are therefore presented as a simplification measure in the meantime. However, adopting common specifications ahead of the forthcoming reform risks creating fragmentation and uncertainty, which makes coordination between the Omnibus IV proposal on common specifications and the planned revision essential to ensure long-term stability and predictability.

## Recommendations

Harmonised European standards should remain the primary instrument for demonstrating compliance with EU legislation. Common specifications should only be used in well-defined exceptional cases.

To use common specifications the following should be considered:

- The preparatory and drafting processes for common specifications should include clearer safeguards to ensure transparency, inclusiveness and legitimacy.
- The timing of extending common specifications should be carefully coordinated with the 2026 revision of the standardisation regulation to avoid fragmentation and uncertainty.
- The international dimension should be clearly addressed, with provisions ensuring consistency with global practices and safeguarding EU competitiveness.
- Copyrights and access issues should be resolved. If common specifications draw on ISO/IEC standards, a sustainable solution is needed to ensure appropriate access while respecting copyright and avoiding legal disputes.

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