



Uncertainty in Standardisation

A systemic risk for the New Legislative Framework and the EU internal market

Recent developments in EU product legislation

The New Legislative Framework (NLF) modernises the EU's approach to product regulation, aiming to strengthen the internal market. It focuses on a common set of legislation for the marketing of products¹, accreditation² and market surveillance³.

In 2022, the European Commission completed an evaluation of the NLF to assess whether the framework remains fit for purpose in light of new challenges such as the green and digital transition. The evaluation confirmed the NLF's core principles but highlighted areas in need of updating:

- Digitalisation and software-driven products: modern products undergo software updates or incorporate AI and connectivity features. The current NLF does not address continuous software changes and needs to ensure compliance throughout the entire lifecycle of software, including the need for updates.
- Circular economy and new value chains: There is a growing emphasis on sustainability and the reuse, refurbishment and remanufacturing of products. The NLF must support sustainable practices while maintaining safety and compliance.
- Digital compliance tools: There is a need to introduce a digital product passport and digital CE marking to modernise how compliance information is provided.

The Regulation (EU) 1025/2012 on European standardisation⁴ sets out the legal framework for standardisation. It governs how standards are developed, adopted and used within the EU. It has recently undergone an evaluation to assess, among other things, the European standardisation system's (ESS) capability to deliver standards in a timely manner that will support a green, digital and resilient EU single market and that will be of global relevance.

¹ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

² Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93.

³ 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) No 765/2008 and (EU) No 305/2011.

⁴ 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.

In March 2024, the European Court of Justice of the EU (ECJ) ruled in the *Malamud* case⁵ that there is an overriding public interest in free access to harmonised European standards (hEN). This has created uncertainty around the financing model and copyright of standardisation organisations, the functioning of the European standardisation system – and consequently also the NLF.

This uncertainty threatens the availability of harmonised European standards, which are a cornerstone of the NLF. Without a sustainable model for developing high-quality, consensus-based standards, the EU risks losing a key tool that allows legislation to remain technology-neutral. By relying on harmonised European standards, EU legislation does not have to specify technical details, which may become quickly outdated. These technical details are instead specified in harmonised standards developed by experts from industry, academia, consumer groups and other stakeholders and can be used by companies to demonstrate compliance with essential requirements in EU legislation.

The decision by the Court of Justice of the EU also casts uncertainty over the EU's ability to deliver on its commitments to the green and digital transitions. Harmonised standards are essential for ensuring that evolving digital products, such as connected devices and AI systems, continue to meet safety and performance requirements throughout their lifecycle. These standards also provide the technical backbone for implementing key environmental legislation, such as the Ecodesign for Sustainable Products Regulation.⁶ If the development or accessibility of these standards is disrupted, it could undermine both regulatory clarity for businesses and the EU's broader policy objectives on sustainability, circularity and digital innovation.

Scenarios and considerations for future reform of the NLF

The NLF has been a foundational model for EU product legislation since 2008. As the EU faces transformative shifts in digitalisation and the green transition, the NLF must be refreshed if it is to remain fit for purpose. The NLF needs to address relevant challenges related to the green and digital transition, such as:

- lifecycle compliance, including post-market software updates, AI retraining and cybersecurity patches,
- the introduction of clearer roles and responsibilities for economic operators when products are modified after entering the market (e.g. repairers, refurbishers).
- the inclusion of more robust tools for sustainability conformity, especially under new frameworks like the Ecodesign for Sustainable Products Regulation.

As we understand, the Commission is considering how the NLF could serve as a horizontal backbone for new requirements, such as the introduction of a digital product passport and digital CE marking to modernise the way compliance information is provided. This could be achieved through a proposal that is not a standalone regulation but a package of amendments to existing sectoral legislation that is harmonised under the NLF, so called “omnibus”. This approach aims to ensure coherence across different legislative frameworks and improve the effectiveness of the NLF as a whole.

⁵ Public. Resource. Org Inc, and Right to Know CLG, C-588(21 P).

⁶ Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC.

If the NLF is revised in a substantial way, there may indeed be a need to revise Decision 768/2008/EC on a common framework for the marketing of products, since that decision is one of the core pillars of the NLF. It provides the common legal framework for definitions such as manufacturer and placing on the market, conformity assessment procedures, obligations of economic operators and rules on CE marking. A modernised Regulation 765/2008 on accreditation could provide the necessary legal and procedural tools to maintain trust in the accreditation and conformity assessment system, even in cases of uncertainty.

More information about the Commission's plan is expected to be included in the upcoming Single Market Strategy.

Due to an evolving regulatory and technological landscape, the European Court of Justice ruling in the *Malamud* case presents significant challenges to the implementation of the NLF. While the European Commission has announced that, as part of the EU's Competitive Compass, a revision of the EU Regulation on Standardisation is expected by 2026, it remains unclear whether this reform will adequately address the legal uncertainties triggered by the ruling.

The ECJ ruling has introduced significant uncertainty, particularly regarding copyrights. The Commission has interpreted the judgment as requiring free public access to all harmonised standards, including those derived from international standards. This interpretation, which excludes compensation to the standardisation organisations for their work, poses a challenge to the financial sustainability of the European standardisation system.

In response, the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) have filed a legal action before the ECJ, challenging the Commission's decision and its assertion that public access even to international standards, is of overriding public interest and must therefore be made fully accessible.

Harmonised European standards remain essential to the functioning of the NLF and advancing the EU's green and digital objectives. They act as a vital bridge between policy and implementation, enabling industry to meet evolving regulatory demands while maintaining legislative clarity and flexibility. In a time of rapid technological and environmental change, a robust and responsive standardisation system is not merely beneficial, it is foundational to the integrity and effectiveness of the EU's quality infrastructure.

To maintain a functional European standardisation system, a balanced and strategic response is essential – one that safeguards the core strengths of the current model while addressing the legal and copyright implications raised in the wake of the Court's ruling. This could involve clarifying the legal status of harmonised standards, ensuring a sustainable financing model for standardisation organisations, and developing mechanisms to guarantee both access and quality in the use of standards supporting EU legislation.

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