



### Harmonised standards

**This paper concerns bottlenecks in harmonised standardisation, causing high compliance costs for companies and delays in market entry.**

#### CONTEXT

Harmonised European standards (hENs) represent a consensus by stakeholders on how to meet market needs, while at the same time they facilitate compliance with EU legislation and support the circulation of goods in the Single Market. Following case law from the CJEU, the Commission started to interpret their role in the system for harmonised standards in a more extensive manner. This has aggravated not only an existing backlog of the publication of harmonised standards, but also includes more prescriptive standardisation mandates. The result is a situation where standards are not available to the users, and manufacturers have to resort to alternative and often costly ways to demonstrate compliance with EU law. This prevents using the potential benefits of Single Market governance, as it unnecessarily complicates EU market access.

#### LEGAL FRAMEWORK

The problem in this case is caused by a contested Commission interpretation of CJEU rulings. The legal framework for European standardisation is set out in Regulation 1025/2012, but this Regulation leaves some leeway as to what the roles of the different actors are in practice (notably Article 10). In principle, the Commission provides the mandate on the basis of which the European Standardisation Organisations (ESOs) develop the harmonised standards with stakeholders. At the end of the process, the Commission also publishes a reference to the hEN in the OJEU, which is necessary for the presumption of conformity to take effect. However, following case C-613/14 (James Elliott) on construction products, the Commission strengthened its oversight on this process by providing more prescriptive mandates and stricter controls before the publication of all hENs. The interpretation of the Commission's responsibilities, and in particular also extending the implications of this case to *all* harmonised standards, remains contested.

#### IN PRACTICE

The current situation causes severe challenges for company compliance processes relating to the EU market. Much of the additional burden and legal uncertainty will stay invisible for the external beholder, as they are distributed inside each company.

- **Absence of harmonised standards.** In the absence of a hEN, companies need to demonstrate compliance by creating a technical dossier with risk analyses that essentially repeat, for every individual product design, what standards already



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prescribe as due risk coverage. This is costly and time consuming and will often involve engagement of a notified body. But even after involvement of a third party in the conformity assessment, the manufacturer is faced with legal uncertainty about acceptance of this evidence by market surveillance authorities in the EU. In the majority of cases (except where products are subject to pre-market approval), the product may easily be taken from the market which causes enormous turnover loss, reputation damage and recall costs. Modifying a well-established compliance process is in itself a substantial burden as well.

- **Link with international standards.** Delays in the harmonisation process mean that the EU adopted version of the standard will run behind the international state-of-the-art standard. Nowadays, that is often the case for more than two or three years. This causes at least a duplication of demonstrating compliance, and oftentimes the need for an EU specific version of the product, or even worse a change to the design and/or manufacturing processes resulting for example in different product lines for different markets. Where mandates for harmonisation do not offer sufficient possibilities to include market-relevant elements linked to international standards, technical differences between EU requirements and those of most other markets even get a permanent character.

While companies will ultimately strive to overcome these challenges, the lack of harmonisation brings additional costs and decreases safety, as there are no detailed uniform requirements for new technologies anchored in standardisation. It also enhances the risk of diverging technical content between EU and international standards, thereby decreasing European competitiveness.

## HOW TO ACHIEVE BETTER RESULTS

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BusinessEurope recommends the **Commission to refrain from assuming additional responsibilities in the harmonisation of standards** where those affect the roles of other key players in this system, as also reflected in our [joint industry recommendations for effective harmonised standardisation](#):

1. Harmonised European standards should be put back in the hands of self-regulating stakeholders, with public authorities at EU and national level in a guiding and guarding role rather than the driving seat.
2. There should be **no bureaucratic interference with planning and execution** of standardisation work by the Commission, and **no excessive setting of requirements for standards** that are incompatible with the nature of standardisation. It is key that there is sufficient **flexibility for stakeholders in the process** as to how achieve ends.
3. The backlog in the citation of harmonised European standards in the Official Journal should be eliminated, and **a swift citation modus should be guaranteed** in the future, which will allow their use for the presumption of compliance by industry.

## CONTACT INFORMATION

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Martynas Barysas, Director, Internal Market Department [m.barysas@businessseurope.eu](mailto:m.barysas@businessseurope.eu)