

European harmonised standards: voluntary rules or legal obligations?

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Series: EU Harmonised Standards: Behind the Scenes of Private Rule-making

‘We must find an effective method to harmonise the technical barriers which hinder the free movement of goods between Member States’, claimed the Commission in 1985. Nowadays, if a manufacturer wants to enter the EU internal market, its products must comply with certain minimum safety and procedural requirements, known as the European harmonised standards (ENs). This is the case for all products requiring a CE marking within the EU, ranging from cableways, machinery and toys, to medical devices and personal protective equipment (such as face masks).



Even though these procedures have been a recurrent practice for a few decades, few people actually know how they are being transcribed, or what happens behind the scenes of private standard-setting organisations. Are they considered compulsory legal standards, or mere voluntary rules? Who is behind the decision-making process of establishing the standards? What role did the standards play in recent years?

This series of three blogs aims at answering some fundamental questions with regards to European harmonised standards.

1. This blog will first delve into the nature of the standards, by establishing its disputed legal personality and the mechanisms used to ensure conformity.
2. The second blog of this series, will tackle the role European harmonised standards played in recent years, with a peculiar focus on their use and relevance during the Covid-19 pandemic.
3. In the last blog of this series, the current challenges coming with the use of European harmonised standards are highlighted, despite their dominant role within the EU economic recovery.

Where do European harmonised standards come from?

The necessity for ENs was expressed as part of the *spillover* effect with regards to European economic integration, playing a role in the efforts to ensure the further deepening of the single market. They were seen as a way to ‘foster the economy of the European Single Market, and enhance the welfare of European citizens by providing an efficient infrastructure to interested parties[1].

In practice, the legislative acts written by the Council and/or Parliament are only able to picture the requirements of general interest of a product. This framework is insufficient to ensure adequate precision and expertise with regards to the description of a specific product, as politicians are no technical experts and vice versa. The Commission thus decided to refer the detailed definitions of technical aspects to private organisations, or standard-setting organisations[2].

Standards are then elaborated within private technical bodies and are sent to the Commission once completed. If the standards are considered

to be in compliance with EU law, their reference will be published in the Official Journal of the EU. Finally, once a manufacturer decides to use these standards, it will receive the required CE marking on its products after the conformity assessment has been conducted. If this is completed, the entry of those products to the market cannot be limited by the Member States!

ENs: voluntary private rules, or extension of EU law?

Since these European standardisation organisations (ESOs) are private in nature, ENs cannot be considered as legally binding and remain voluntary in nature. This is further enhanced by the fact that the manufacturer must pay copyright fees if they wish to access the content of standards, which would not be the case if these were considered public law. An economic operator can always prove conformity with the essential requirements laid down in legislation in a different way than through the application of ENs. For instance, an economic operator wishing to sell face masks does not have to apply EN 14683:2019 related to medical masks if they can prove compliance with Regulation (EU) 2016/425 through other means. Once a successful test of conformity has been conducted, with or without the use of EN, manufacturers have to include the CE marking on those products.

Would one then consider ENs as a purely non-binding private process? Even though ESOs are private entities in nature, they also have a considerable impact on rule-making[3].

1. ENs were judged as being part of EU law in the *James Elliott* case[4].

Despite the lack of a binding effect of ENs, national courts and tribunals often refer questions on their interpretation to the Court of Justice of the EU through the preliminary ruling procedure, even though Article 267 TFEU does not cover acts of private-law bodies.

2. They provide manufacturers with means to presume conformity with the requirements, through the legally binding ‘presumption of conformity’. If the manufacturer decides not to use ENs, it bears the burden of proof to satisfactorily demonstrate that an alternative standard or methodology provides an equivalent or better level of safety than that provided by the harmonised standard[5].
3. European harmonised standards are being advertised as the main *go-to* solution in a majority of Member State’s national websites. Looking at the *Dutch Government Information for Entrepreneurs* page, the checklist for getting a CE marking starts with ‘Find the harmonised standards that apply’, not informing the individual that other ways to prove conformity are also allowed.

Overall, it can thus be stated that European harmonised standards cannot be considered as rules belonging exclusively to the private sphere. They are the most promoted and easiest to access to get your product certified for the internal market, and are also able to be the subject of a preliminary reference to the Court.

What you can expect from our upcoming blogs, later in this series?

The peculiar position of ENs within the legal order raises some concerns with regards to the principle of participation and transparency, key to the EU rule of law. Can the Commission ensure enough supervision over private standard-setting organisations? To what extent can ENs be challenged in Court to ensure sufficient judicial protection? How did Covid-19 and emergency measures concerning market access change the status quo for the use of ENs within the EU? These questions will be answered in the following blogs of this series.

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The views expressed in this blog are those of the authors and not necessarily those of EIPA.

References

[1] Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets*. Oxford: Hart Publishing, 2005. Also: book review in *Common Market Law Review*, 2005, pp. 600-603.

[2] At the EU level, the private standardisation organisations are known as **CEN** – providing a platform for the development of European standards and other technical documents on various types of products, materials, services and processes, **CENELEC** – responsible for standardisation in the electrotechnical engineering field and **ETSI** – producing globally

applicable standards for information and communications technology.

[3] Mariolina Eliantonio and Annalisa Volpato, 'Legal Opinion on the European System of Harmonized Standards'. *ECOS*, 2021, p.4.

[4] *James Elliott Construction Limited v Irish Asphalt Limited* (2016)

[5] Laura Degallaix and Mariolina Eliantonio, 'How to Ensure a Legally-sound and Socially-acceptable Use of Standards by Policy-makers in View of the CJEU James Elliott Ruling and Other Court Cases', 06-2019, *ECOS*, retrieved via <https://ecostandard.org/wp-content/uploads/2018-06-11-The-use-of-standards-in-legislation-and-policies-ECOS-discussion-paper.pdf>, last visited on 10 January 2022.