

European Harmonised Standards: Most Appropriate Regulatory Technique in Times of Crisis?

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

Standardisation bodies like CEN and CENELEC continue to play a vital role not only in powering the Single Market, but also in Europe's recovery and transition to a green and digital future.

- Director General Elena Santiago Cid – CEN and CENELEC

This series of blog posts tackles the topic of EU Harmonised Standards (ENs). So far, the series has approached the nature of this regulatory technique, its mechanisms and its use during the pandemic. The pandemic, for instance, has shown that dealing with healthcare could not solely be done at the national level. ENs offered a way to harmonise and secure the entry of products into the market. Moreover, CEN and CENELEC assert that ENs will be part of Europe's recovery towards building a more robust and resilient economy post-crisis. Yet, this assertion does not mean that the current standardisation framework cannot be improved, or that reforms are not needed. The debate of altering the regulatory framework of ENs has divided legal scholars and interested parties in the last few years. This has resulted in an interesting exchange of arguments for and against. Should the current regulatory framework for ENs change now that Europe enters a period of economic recovery? And if so,

how? This article will cover different prospects for potential ENs reforms – such as the necessity to enhance their legitimacy, the accountability of ESOs or a fairer access to ENs – seen from two different points of view.

We shouldn't open the 'Pandora's Box' of harmonised standards

Bardo Schettini Gherardini, former Director of Legal Affairs of CEN and CENELEC, is on the side of those opting to keep the current established framework. In 2016, he defended an opinion in the European Law Blog stating that there should be no requalification of the ESOs as EU bodies, or ENs as EU acts. His reason was that it would open a Pandora's Box (Article 267 TFEU) for any other private activity connected to EU law. Gherardini illustrates this standpoint by referring to three main arguments.

First, he emphasises that ENs remain voluntary in nature. Their publication does not prevent an economic operator from proving compliance through means other than the relevant technical standards. This first point illustrates the competing views regarding the nature of ENs. ESO members are convinced that ENs are subject to private voluntary rules, initiated through private regulation. Other legal scholars understand the dimension of co-regulation via a process of delegated rule-making. Yet, we could easily challenge this voluntary nature by referring to the de facto binding nature of EN, which we explained in the first blog post.

Second, he highlights that ESOs are not institutions, bodies or agencies of the EU. This would also mean that ESOs should not be subject to the same actions or controls, due to their private nature. This argument can be supplemented by reference to the Meroni doctrine. This doctrine limits delegative powers to bodies or agencies of the EU, but not to private bodies such as CEN. Yet, it is also possible to challenge this point. Even it is not possible to debate the private nature of ESOs, ENs become adopted on the Commission's

initiative. Moreover, the Commission itself grants the presumption of conformity to ENs by their publication in the Journal. To a certain extent, ESOs still operate under the supervision of the Commission.

Third, he argues that ENs are currently the fastest options known to supplement EU legislation with the required level of expertise. There have been attempts to include standards in EU law and these have been proved to slow down the process. On the one hand, we could dispute this part of the argument. In the end, even ENs were put aside during the pandemic to ensure faster production. Economic operators had a green light to put PPE on the market even if the products[1] were not fully in line with the corresponding ENs, as seen in the last post. On the other hand, Gherardini has a point when stating that merging standards into EU law has slowed down the whole regulatory process. If the European Commission decides to slowly confer the status of law to ENs, it intensifies its own accountability regarding their content. To protect itself at the judicial level, it has already started to hire several HAS consultants who monitor the standards independently from ESOs. Yet, this additional safeguard is slowing down the approval of new standards, including the one for medical devices. For instance, the crucial 'healthcare engineering' department had four HAS consultants working under the instructions of the Commission. When the pandemic struck this was seen as insufficient, as a speedier approval of standards was required.

Hence, we can debate Gherardini's opinion on different points. Reforms of ENs can still be considered as conceivable – despite recognising certain limitations – especially if such reforms want to play a bigger role in the future. Even though the debate between seeing ENs as private rules or extensions of EU law is still ongoing, this analysis points towards seeing them as more than merely confined to the private sphere.

A stronger stance, but how?

... the twin pillars of administrative democracy, transparency and participation, are still a matter of concern when analyzing the regulatory technique of European Harmonised Standards.

- Eliantonio and Volpato (2021)

What aspects of ENs could we change to ensure their legitimate position in EU rule-making in the upcoming years? The pandemic seems to have pushed for three different avenues of prospective reforms: the removal of copyright charges on ENs, the relations with ISOs and the need to clarify the extent of judicial controls.

The first heated topic is the one of **free and fair access to harmonised standards**. ENs are still regarded as products of private intellectual production. This means that economic operators need to pay copyright fees to gain access to them. Conversely, if we can interpret standards as complying with norms in laws and belonging to the public domain, they should be made accessible free of charge. An exception was made during the pandemic [2], but it was used mainly to address the shortage of protective equipment. At the ESO level, organisations would prefer to keep copyrights because these constitute their revenue. However, there is a clear lack of transparency regarding the actual sales of ENs. Bjorn Lundqvist made an interesting proposal; he suggested that ENs should lose their copyright protection while stored in IT databases. ESOs should still obtain fees for accessing digital data through the Commission though, based on sui generis data protection.

The second point the pandemic highlighted is the **importance of further clarifying the legitimacy of other international standardisation organisations** (ISOs) as a valid source of health and safety requirements. A way to increase entry into the market of various international products is to relax regulatory approvals and enforcement procedures at the national level, provided that

safety is not compromised. The Commission's Recommendation 2020/403 of March 2020 supported the opening of the EU market to protective equipment manufactured to WHO recommendations and standards, rather than in strict adherence to EU ENs. This is an opening to further multilevel governance in matters of standardisation during the crisis that could be continued post-pandemic. It would help to move towards an inclusive recovery market at the global level, facilitating trade. Eliantonio and Volpato stressed the importance of encouraging a move towards an internationalisation of standardisation for efficiency reasons. However, it is necessary to first clarify how EU actors could ensure that standards developed internationally still reach the required level of transparency and participation in the process.

The last potential reform had already been extensively debated prior to the pandemic: whether there is sufficient judicial control within the current EN regulatory framework. Following the *James Elliott Case*, the Court had already made a move forward by assimilating ENs as acts of EU institutions within the scope of Article 267 TFEU. It further published the standards in the C series of the *Official Journal of the European Union* [3]. Yet, it has still not been settled how this would affect the right to further ex ante judicial control over the EU standardisation process. In that regard, there should be strong encouragement towards further clarification on the possibility of challenging an EN through an action of annulment under Article 263 TFEU. ENs produce legal effects despite being created by a private organisation, and are being formally referenced in the C series of the Official Journal. Despite it not being a viable option at present, ENs cannot continue to be immune from judicial control. This is due to the development of their legal personality in recent years, and the further role they wish to play in the EU's recovery plans.

Hence, this blog post does not support the statement that harmonised standards could not serve the EU in its path towards a strong economic recovery post-Covid. Rather, it encourages a more transparent way to do so. The pandemic highlighted and reinforced the need to reform this overlooked regulatory framework and encouraged a way towards a more legitimate system of standardisation at the EU level.

Finally, this series of blog posts aims at democratising the creation of ENs at the EU level. This is a process that affects all EU citizens because it touches upon products that we use daily. It explores how the Covid crisis altered the regulatory framework of harmonised standards within the EU. The pandemic highlighted that in times of crises the EU was inclined to step away from the established procedures as a necessary step to enter goods into the market. Instead, certain exceptional measures were put in place to improve the efficient and safe manufacturing of products. ENs released during the pandemic were part of a strong European response. However, future progress in the standardisation process should reflect a better coherence with the rule of law through necessary reforms in the field.

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

References

[1] Note that these products were only meant for medical professionals. Therefore, placing such products in the normal distribution channels was not possible.

[2] See last [blog post](#).