

## Orgalim response to the European Commission Call for Evidence for an evaluation of Regulation 1025/2012

Regulation 1025/2012 is a core pillar of the New Approach; it is an integral part of the New Legislative Framework (NLF) and its evaluation is therefore of great importance for Orgalim. We are fully convinced that **Regulation 1025/2012 is fit for purpose**, and we are committed to contributing to the evaluation process and all its activities, supported by the extensive expertise of our membership on standardisation matters. On the occasion of the Call for Evidence, we wish to reiterate some key elements that shape our views on the European Standardisation System (ESS).

Harmonised European Standards (hENs) play a critical role within the New Approach framework; they represent years of work and cooperation among various stakeholders to reach consensus, and they are pivotal to the effectiveness and efficiency of the New Approach. In this regard, we firmly believe that Regulation 1025/2012 remains well-suited for its intended purpose. If anything, we advocate for the strengthening of the public-private partnership, which is the foundation of the ESS and is essential for ensuring the continued success of the NLF.

For this reason, we remain convinced that hENs are, and must remain, the preferred tool to provide presumption of conformity. The utilisation of common specifications or other certification schemes (such as in the European Commission proposal for the Cyber Resilience Act) should only be considered under extraordinary circumstances and be introduced consistently across new legislation. Comprehensive guidelines should establish stringent criteria, such as a thorough preliminary impact assessment and the necessary consultation and direct collaboration of industry stakeholders.

As we are convinced that Regulation 1025/2012 is fit for purpose, we believe it is crucial to weigh any proposed improvements against the risks associated with altering a well-established system. In our view, rather than changing the Regulation, it is more important to have a more practicable interpretation of certain Articles, e.g. Article 10 (5), to streamline the processes in the European standardisation system

Finally, we would like to emphasise that harmonised standards, despite their consensual development process, are fundamentally market-driven technical specifications representing the state of the art, which are developed and maintained by market actors. As such, they are part of a healthy competitive dynamic, which makes them more than just honorary documents. For this reason, we have concerns regarding the recently published Advocate General Opinion on the ECJ case on the free availability of standards<sup>3</sup>, as it shows a lack of understanding of how the NLF system works. A court ruling following this opinion has the potential to undermine the foundation of the European Standardisation System (ESS) and jeopardise the overall functionality of the NLF.

We look forward to continuing to contribute to the evaluation and to an effective and efficient ESS.

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<sup>3</sup> Advocate General's Opinion in Case C-588/21 P | Public.Resource.Org and Right to Know v Commission and Others