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Call to preserve the EU ‘New Approach’ as one of the Single Market’s best regulatory techniques

Orgalime, which represents Europe’s engineering industries as a whole, calls upon EU policy makers to save the “New Approach to technical harmonisation”, better known as the “CE marking system”, from legalistic and unnecessary bureaucratic measures arising from the Commission’s application of Regulation 1025/2012 on European Standardisation.

Our industry produces some 28% of industrial products in Europe, the overwhelming majority of which benefit from the presumption of conformity with New-Approach-type legislation, by complying with the technical specifications of harmonised standards, representing about two thirds of the portfolio of CEN and CENELEC for such standards and a number of ETSI standards.

For over 30 years, the New Approach, with its twin tracks of essential requirements defined by regulators and harmonised standards developed in the European Standards Organisations serving as a practicable compliance tool, has been the most effective better regulation technique for Europe’s engineering companies and has helped the industry to become more competitive, thereby allowing it to become Europe’s lead manufacturing employer with nearly 11 million staff a turnover of 1900 billion euro and exports representing over a third of the EU’s manufacturing exports. The industry, moreover, is continuing to grow at the level of jobs and output.

The New Approach has successfully supported the free circulation of industrial products within the European Single Market to the overall satisfaction of the EU Member States on all levels including consumer protection and at the level of improving workers’ safety.

Thanks to the New Approach, our industry has easy access to global markets without further technical barriers to trade by using European harmonised standards adopted by CEN and CENELEC further to international agreements with ISO and IEC.

For our industry, it is therefore paramount to ensure that the successful and well established New Approach regulatory technique continues to enable manufacturing innovation in Europe so as to keep it a world leader in many technology areas, thereby driving growth and jobs in the EU.

The New approach - a regulatory model is under threat

Unfortunately, today, the New Approach is threatened to become mired in bureaucracy and to no longer act as a driver of competitiveness: the New Approach has facilitated the operation of the Single Market and is therefore a successful regulatory model, which we believe should be further used and expanded. However, the European Commission’s over-legalistic interpretation of Regulation 1025/2012 (Article 10-6) triggers a lengthy and sometimes unnecessary bureaucratic scrutiny of candidate Standards. The alleged need to match the Commission’s self-instated pre-conditions for the citation of these standards in the Official Journal of the European Union (OJEU) creates unnecessary delays and is depriving all market operators from the benefit of the presumption
of conformity beyond what is reasonable, as evidenced in a recent Case of the Court of Justice of the EU ².

It would be extremely degradable to the future of the New Approach if the European Commission were to consider the European Court of Justice (ECJ) ruling in the James Elliott Construction³ case as applicable to all situations where harmonised standards support the application of EU New Approach harmonisation legislation. It is a preliminary ruling under the very specific EU Construction Products legislation and should not be extended to all other situations.

As a consequence of this legalistic approach, today⁴ the references of 73% of recently adopted candidate harmonised standards are not published in the OJEU compared to 17% that were under scrutiny in 2010. Therefore, our stakeholders that voluntarily contribute their engineers and technical experts time at their own expense to the development of harmonised standards are frustrated; they are starting to lose the motivation to work in any standardisation related activity, especially as adopted candidate harmonised standards are no longer being swiftly cited in the OJEU. These above-mentioned developments, which are harmful to industry – especially to small businesses –, are raising concerns in challenging times where the European engineering industry needs, more than ever, legal certainty, predictability and flexibility in compliance procedures to make the transition to the digitalisation of their business process.

Therefore, Orgalime urgently calls on the European Commission, to take steps to restore the confidence that European manufacturers have started to lose in both the New Approach and the European standardisation system.

We look forward to a revamped dialogue between Commission services and our industry as the primary users of harmonised standards, to build a mutual understanding that harmonised standards are considered as a voluntary compliance tool with applicable EU regulatory requirements for the industry, not as an extension of EU legislation. This would in turn remove any unnecessary legalistic preconditions and formalism from the compliance check procedure prior to citation in the OJEU. Besides, as stressed in Regulation 1025/2012 (Art.10.5), such an assessment should be conducted jointly between the European Commission and European Standards Organisations.

The European engineering industry is committed to facilitate this achievement in the framework of the much welcome Joint Initiative on Standardisation, particularly within Action 8 (Provide high-quality standards delivered and referenced in a timely manner) and with the support of the Standards MArket Relevance Round Table (SMARRT - JIS Action 6).

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2 “It is crucial to make clear (…) that by affixing the CE marking to a product the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility therefore” (Decision 768/2008 (Recital 31). Consequently, the responsibility of the Commission is not engaged in that respect by citing the reference of a candidate harmonised standard in the OJEU. On the contrary, the European Court of Justice ruled recently that the Commission had deprived economic operators from the application of the principle of legal certainty and thereby adversely impacted the general scheme of the New Approach to facilitating the free movement of goods in the internal market: “the Commission position, (…) results in very significantly reducing the number of harmonised standards which can be used during the early part of the application of that [new EU legislation] and therefore adversely affects the effectiveness of the system” (Recital 67 of ECJ Ruling of 28/01/2017 in the Case T- 474/15 that uphold the claim of Global Garden Products Italy SpA (GGP Italy) against the European Commission): http://curia.europa.eu/juris/document/document.jsf?text=&docid=187179&pageIndex=0&doclang=EN
4 Source: CEN and CENELEC Management Centre – Standards offered to the EC for citation in 2015 vs. 2010.