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Position on the listing of harmonised standards and information on the state of the art in Europe

1 Situation

For several years, European industry has been confronted with an increasingly problematic practice regarding the publication of harmonised standards in the Official Journal of the European Union (OJEU) by the EU Commission. Delays in the publication or the non-publication of the current versions of relevant standards have become significantly worse, leading to considerable legal uncertainty for manufacturers, especially small and medium-sized enterprises (SMEs), and market surveillance authorities, as well as to a significant increase in bureaucracy.

The change in the EU Commission's practice is a direct consequence of the James Elliott ruling by the European Court of Justice (dated October 27, 2016, C-613/14), according to which harmonised standards are part of EU law. This is mainly justified by the legal effect of the so-called “presumption of conformity” triggered by their listing in the EU Official Journal. Since then, the EU Commission has effectively regarded harmonised standards as extended legal provisions.This development has far-reaching legal, technical, and economic consequences.

At the same time, harmonised standards play a key role in EU product regulations, particularly in those based on the New Legislative Framework (NLF). They provide solutions, concepts, and procedures for expressing in technical terms the “essential requirements” formulated as abstract protection goals[1]. As the EU Commission itself has repeatedly emphasized, they are intended to reflect the state of the art in Europe that is relevant for determining the required level of safety and conformity. As explicitly stated in its guide to the implementation of EU product regulations, the so-called Blue Guide[2], “the concept of essential requirements (...) is based on the assumption that harmonised standards reflect the generally recognized state of the art (...)”.

2 Objective

Our aim is to emphasize the well-established NLF system, which has functioned very well for many years, including the presumption of conformity associated with listed harmonised standards, as well as to put forward a constructive solution that also includes such harmonised standards that correspond to the state of the art but are not listed in the EU Official Journal.

The key priorities are to:

- strengthen the role of the state of the art in Europe as the relevant benchmark for the application of the essential safety requirements of EU product safety law,
- ensureg innovation capacity and technical diversity,
- improve legal certainty for manufacturers and strengthen the uniform enforcement of European product rules by market surveillance authorities,

[1] Article 3(2) of Decision 768/2008/EG

[2] Blue Guide Chapter 4.1.2.4

- preserve the voluntary application of standards.

3 Challenges

3.1 Legal interpretation of harmonised standards

The legal view that harmonised standards are part of EU law and should therefore be treated as extended legal provisions in practice often leads to the following:

- Formal legal criteria dominate technical assessments.
- Assessments by non-experts influence or even replace technical specifications.
- Necessary technical flexibility is restricted.

This hinders innovation and puts innovative European companies at a particular disadvantage in global competition.

3.2 Standards listed in the EU Official Journal often do not correspond to the current state of the art.

Since the James Elliott ruling, a large proportion of the harmonised standards listed in the EU Official Journal are technically outdated and no longer reflect the current state of the art. In practice, this is less due to technical issues in the standards but more to formal and legal requirements in the review process for listing in the EU Official Journal. Among other things, this leads to the following:

- There are no suitable assessment criteria available for new or complex technologies.
- The uniformity of the application and enforcement of EU product legislation suffers among all stakeholders (manufacturers/economic operators; conformity assessment bodies; market surveillance authorities).
- Manufacturers incur significant additional effort to determine, analyze, and demonstrate conformity with the current state of the art (with reference to standards listed in the Official Journal).
- The international acceptance of the European market access system and the markings (CE marking) and declarations (EU declaration of conformity) based on it suffer.

This results in considerable legal and planning uncertainty for manufacturers. From the perspective of both EU product and liability legislation, proof must be provided that the current state of the art in Europe has been met. In practice, this means that the application of a harmonised standard listed in the Official Journal alone is often not sufficient, so that current standards and technical specifications that actually reflect the current state of the art in Europe must be consulted in addition.

3.3 Overviews of the state of the art, maintained by European industry associations

Since there are many areas in which listed hEN no longer reflect the current “state of the art,” it is necessary to build a robust bridge between regulatory requirements (essential protection objectives in EU legislation) and the practical application of current assessment criteria (unlisted harmonised standards, international product standards).

For this reason, European industry associations have launched initiatives aimed at compiling relevant product standards that represent the current state of the art in a transparent manner and making them available (e.g., the CAPIEL[3] initiative). These approaches provide a valuable practical resource, particularly for small and medium-sized enterprises, but can only offer supportive and temporary guidance. Pure listings by industry associations without involvement or recognition at the European level cannot replace a structural solution and carry the risk of fragmentation.

[3] CAPIEL

Proposed solution: Listing of harmonised standards in the EU Official Journal by the European Commission, supplemented by official information on the state of the art in Europe.

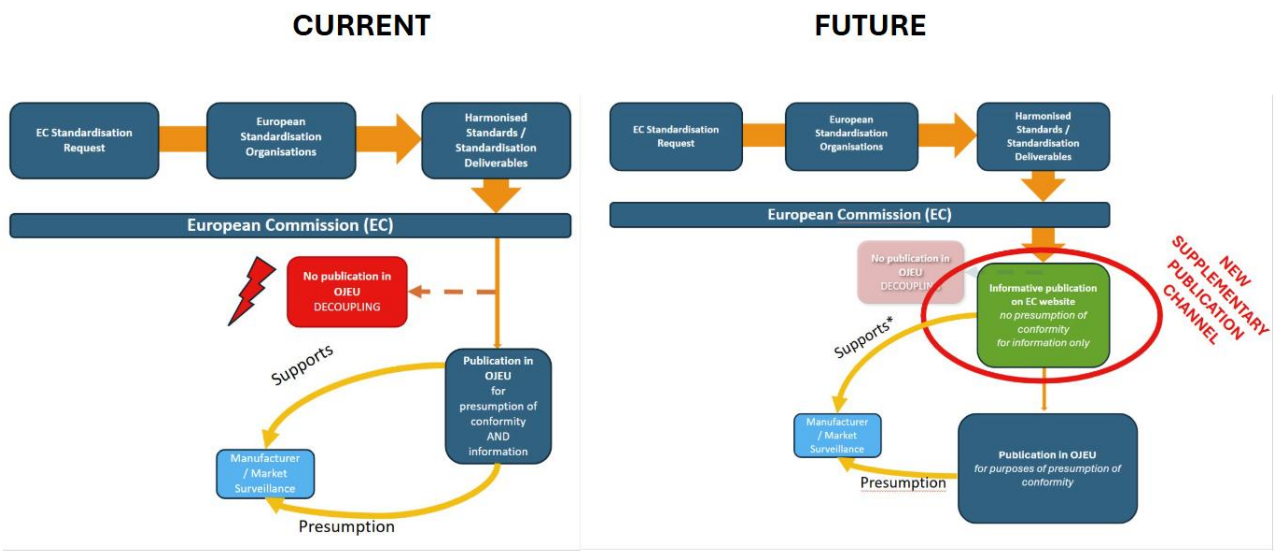

Illustration 1: Comparison of current vs. future hEN listing process

The aim is to ensure the long-term functioning of the proven New Legislative Framework (NLF) system. Harmonised standards should reflect the current state of the art in Europe. We therefore propose supplementing the established procedure for drawing up and listing harmonised European standards to the effect that the Commission initially publishes the references of such harmonised standards submitted by the ESOs for information purposes, without further examination of their content. Formal presumption of conformity would continue to take place only after examination and listing in the Official Journal:

a) Listing in the EU Official Journal (with presumption of conformity)

Harmonised standards should continue to be listed in the Official Journal of the EU in order to enable technology-related specification of European Directives and Regulations and to provide legal certainty, which is equally important for manufacturers and other economic operators as well as for market surveillance authorities. Such listings should continue to be included in the L series of the Official Journal.

b) Additional information on the state of the art in Europe

Harmonised standards that have been drawn up or adopted by the European standardisation organisations (ESOs) on the basis of a standardisation request from the European Commission should be published by the EU Commission for the purpose of providing information on the current state of the art in Europe. This should be done either in the C series of the Official Journal or directly on the Commission's website (as part of the information on the application and implementation of each EU product legislation). Since this publication does not trigger a presumption of conformity in the legal sense, the standards do not become part of EU law, which means that questions regarding licensing rights and copyright (e.g., Malamud ruling) are irrelevant.

This would be a significant help, particularly for SMEs, in the technical implementation of CE marking. The publication of such technical specifications would be for information and guidance purposes only and would explicitly not establish a “presumption of conformity” within the meaning of the NLF. The sole aim is to promote clarity and consistency in the technical assessments without creating new legal obligations.
If, from a legal point of view, publication in the C series is not possible, the European Commission should alternatively provide corresponding overview lists on its website or at least refer to overviews maintained by the European Standardisation Organisations (ESOs).

4 Conclusion

Greater recognition and transparent consideration of the current state of the art in Europe is in the central interest of European product legislation. It is a prerequisite for:

- Innovation,
- Safety,
- Competitiveness of European companies,
- Uniform and appropriate enforcement.

An informative, non-legally binding compilation of relevant standards and normative documents represents a pragmatic solution to this problem, strengthening both legal certainty for economic actors and the uniformity of enforcement of European product law.

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