

# INCREASED COMPLEXITY IN CE RELEVANT STANDARDS

HOW THE EU COMMISSION'S CHANGED PUBLICATION  
PRACTICE UNSETTLES MANUFACTURERS AND WHAT  
SPECIFIC STEPS YOU SHOULD TAKE

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# BACKGROUND

Even before the Radio Equipment Directive 2014/53/EU was published, it had become clear that there are obviously problems with the prompt provision of harmonized standards in the Official Journal of the European Union. The reasons for the delay are neither transparent nor comprehensible for standards users.

Four reference documents are significant here:

- The Blue Guide 2016 <sup>[1]</sup>,
- The Standards Regulation (EU) 1025/2012 <sup>[2]</sup>,
- The ECJ's James Elliott judgment
- The CFI's Global Garden judgment <sup>[5]</sup>.

The three latter documents have had a huge influence on the way harmonized standards are published by the Commission, which presents challenges for the Commission itself and for the European standards organizations CEN, CENELEC and ETSI.

On July 12, 2018 a workshop on this topic was held in Brussels with the Commission, CEN and CENELEC. The Commission's key statements can be summarized as follows:

1. Starting in 2008 the standards system was developed further based on the "New Approach" and organized in a more structured way. The reason for this is to safeguard the legitimization of standards created by the private sector and the related legal effects.
2. The ECJ's James Elliott judgment gives the Commission more extensive responsibility related to the assessment and approval of harmonized standards for publication in the Official Journal of the EU.
3. Consequently, in accordance with Art. 10 (5) of Regulation (EU) 1025/2012, the Commission must assess whether a harmonized standard actually satisfies the essential requirements it covers in the context of the standardization request (mandate). Since the James Elliott judgment, the Commission has to do this in a more formal manner.
4. In accordance with Art. 10 (6), the respective harmonized standard is not published in the EU Official Journal until it satisfies these requirements.
5. However, there have not yet been any detailed requirements or regulations listing criteria for deciding which harmonized standards are to be published in the EU Official Journal. This is to be changed.

6. But as the Commission does not have the expertise required to compare the original standardization request with the standardization results, it commissioned an international business consulting company [6] that functions as a so-called "HAS (Harmonized Standards) Contractor". This contractor selects HAS Consultants (who have replaced the New Approach Consultants) and charges them with assessing the standardization results in accordance with Art. 10 Section 5 of Regulation (EU) 1025/2012. They therefore ensure that the standardization results actually satisfy the essential requirements they cover, in connection with the harmonization legislation referenced. Once this compliance assessment has been successfully completed, the respective assessed standards are published in the EU Official Journal. However, this process is more time-consuming than before, with the result that although many standards have been published, for much harmonization legislation no new references have been published.

7. As a further consequence in connection with the Global Garden judgment, the Commission must explicitly assign a presumption of conformity to a harmonized standard, or, in the case of a subsequent objection, restrict the presumption of conformity for the relevant sections of the standard, or explicitly withdraw the presumption of conformity from a harmonized standard.

8. In addition, the Commission has been using a different publication practice since December 8, 2018. From that date, new harmonized standards or harmonized standards with a restricted presumption of conformity, as well as harmonized standards from which the presumption of conformity has been withdrawn (because, for example, the transition phase has ended) are published in Official Journal L (Legislation) in a so-called implementing decision.

9. What is more, in the case of some harmonization legislation the previous overall lists of references to harmonized standards have been removed from EU websites (for example in the case of the Machine Directive).

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