NLF interpretative Fiche

Orgalime Position Paper

Title Short:

Application of CA modules: content of the Technical Documentation

Fiche Nb: **11**

Subject:
The required minimum contents could develop into disproportionate bureaucratic burden

Last Update:
18-03-2011

Category:
Accreditation and conformity assessment

Legal basis:
Decision, Annex II (Conformity assessment procedures)

Legislative references:

- **Regulation No 765/2008/EC** of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation No 339/93/EEC – Published in the OJEU L 218/30 of 13/08/2008
- **Decision No 768/2008/EC** of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC – Published in the OJEU L 218/82 of 13/08/2008
- **Council Decision of 22 July 1993** concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives 93/465/EEC

ISSUES TO BE ADDRESSED:

1) The "minimum contents" of the technical documentation to be established by the manufacturer which is newly required in Annex II of Decision 768/2008/EC could develop into a very burdensome and disproportionate bureaucratic requirement (also considering the possible need for it to be translated, cf. Decision, art. R2.9, R4.9). [1]

2) There is a new explicit requirement for inclusion of an "adequate analysis and assessment of the risk(s)" in the technical documentation. However, this is normally carried out in the harmonised standards.

SOLUTION ENVISAGED:

Re. 1): It should be clarified that the expression "wherever applicable" should be interpreted to mean "as far as relevant for assessment" (as correctly formulated in Decision 93/465), as the purpose of the technical documentation is to allow proper assessment by notified bodies and/or market surveillance.

Re. 2) It should be clarified that the new explicit requirement for an "*adequate analysis and assessment of the risk(s)*" does not require manufacturers to make an additional risk assessment or to draw up additional documentation, if they have applied harmonised standards the development of which is based on an assessment of the relevant risk(s). Manufacturers may base their assessment on harmonised standards, which already include the risk analysis.

[1] See also our NLF interpretative Fiche Number 3 (Translation of the Technical Documentation)

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