NLF interpretative Fiche

Orgalime Position Paper

Title Short:

Proportionality of conformity assessment

Fiche Nb: **8**

Subject:
Different treatment depending on size of undertaking concerning conformity assessment

Last Update:
18-03-2011

Category:
Accreditation and conformity assessment

Legal basis:
Regulation, art 8.10 and Decision, art 4.4 and R17.6(c)

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

ISSUE TO BE ADDRESSED:

According to the Regulation a national accreditation body shall ***verify*** that conformity assessment is carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on companies and that due account is taken of the size of the company, the sector in which it operates, etc. The term “verification” needs to be clarified in terms of requirements for the accreditation bodies.
Similarly, it is necessary to clarify the interpretation of art 4.4 of the Decision, which states that "*for custom-made products and small series production, the technical and administrative conditions relating to conformity assessment procedures shall be alleviated*". The application of this provision may lead to diverging procedures for conformity assessment depending on the kind or size of the undertaking involved. Similar concerns are raised by art R17.6(c) of the Decision, which requires conformity assessment bodies to perform their activities “*taking due account of the size of a company, the sector in which it operates, its structure, the degree of complexity of the product technology in question etc.*”

SOLUTION ENVISAGED:

Product safety should not depend on the size of the manufacturer or of its undertakings, and there should be no special rules for SMEs as far as the affixing of CE marking and the underlying obligations it imposes are concerned. It is therefore necessary to clarify that the proportionate approach to conformity assessment, as required in these Articles, does not imply any compromise on the level of safety. In particular,

- For the requirement in art 8.10 of the Regulation, there is a need to ensure a harmonised approach, possibly through an EA guidance document

- For the requirements in art 4.4 and R17.6(c) of the Decision, a distinction is necessary:
  - ↳ Regarding the Modules using quality assurance (Modules D, E, H, and their variants), their application needs to be adapted to the size of the undertaking, as is already required by the relevant standard EN ISO 9001.
  - ↳ Regarding Modules B (EC-type examination), F and G, these are product-related conformity assessment procedures, and therefore their application (i.e. the examination of

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a product type/batch) must not be made dependent on the size of the manufacturer's organisation.