

Title Short:

Imprecise definition of accreditation

Fiche Nb:

5

Subject:

Accreditation in support of notification: imprecise definition of accreditation

Last Update:

18-03-2011

Category:

Accreditation and conformity assessment

Legal basis:

Regulation, art 2.10 and Decision, art. R17, R18

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 art 2 paragraph 10 of the Regulation, “accreditation” shall mean an attestation by a national accreditation body that a conformity assessment body (CAB) meets *the requirements set by harmonised standards* and, where applicable, any additional requirements, including those set out in relevant sectoral schemes to carry out the specific conformity assessment activities. This definition is imprecise insofar as the term “the requirements” could be limited to those standards requirements that correspond with the requirements for conformity assessment bodies listed in art R17 and R18 of the Decision, the fulfilment of which provides presumption of conformity according to Article 3 paragraph 2 of the Decision (and therefore, for example, might not include requirements for QMS). Such an interpretation would lead to different accreditation systems for the regulatory and non-regulatory areas – where full compliance with all requirements of the relevant standards is obligatory for accreditation – which is exactly what the Regulation seeks to avoid. Accreditation has been given a referential position because of its being based on a consistent system as determined by the standards for CABs which are accepted in the market place and rely in particular on the efficient implementation of an appropriate QMS by the CAB. This is why it is necessary to minimise the impact of imprecise definitions that may lead to varying interpretations and consequently to two (different) types of “accreditation” with a different coverage when used for the purpose of **notification**.

SOLUTION ENVISAGED:

The term “the requirements” in art 2 paragraph 10 of the Regulation should be clarified to mean “**all** the requirements” set by harmonised standards.¹

¹ This is in line with the relevant statements in all SOGS documents preceding the Commission proposal, and was still included in the version of the proposal that went into inter-service consultation.