



EUROPEAN COMMISSION  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
New Approach Industries, Tourism and CSR  
**Standardisation**

# *Vademecum on European Standardisation*

## Part II

European Standardisation in support of European policies

### Chapter 3

#### **Models of articles on standardisation issues to be included in drafts of New Approach directives**

15 October 2009

**Status of the document:** Final

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## MODELS OF ARTICLES ON STANDARDISATION ISSUES TO BE INCLUDED IN DRAFTS OF NEW APPROACH DIRECTIVES

### I. New Approach legislation

#### 1. *The New Approach as a legislative technique*

The “New Approach” was born on 7 May 1985. It moved away from the “Old Approach” of prescriptive detailed technical requirements written into the legislation. The New Approach is a legislative technique which limits harmonisation to essential requirements. These “essential requirements” are in particularly health and safety requirements for products. This simplification was a step forward in the legislative provisions, allowing all the technical elements for product specification to be covered in harmonised European standards, not the legislation itself; thus providing a flexible, technology-neutral and non-prescriptive means of regulation. A manufacturer therefore has the flexibility in how to conform to the requirements and to demonstrate compliance. The final step is that the manufacturer applies the CE marking to identify that the product complies with the law. The New Approach is a legislative technique used in the area of free movement of goods, particularly of industrial products.

Parallel to its legislative programme, the Community also developed a policy to reinforce European standardisation in order to develop voluntary harmonised European standards, conformity with which gives presumption of conformity with relevant legislative provisions.

#### 2. *New Legal Framework*

In 2008, a new package of measures which are intended to boost intra-community trade in industrial goods was adopted. These measures will ensure that the internal market does indeed become a reality for all manufacturers and producers, and will make it easier for companies, especially SMEs, to trade their products in the Union. High quality safe products will continue to be the goal, whilst ensuring market access for goods.

This new package of measures includes also Decision No 768/2008/EC on a common framework for the marketing of products<sup>1</sup>. Decision No 768/2008/EC provides a toolbox of measures which will, in future, be integrated into the legal framework as sectoral specific New Approach directives are adopted, revised or updated. This will give the means to clarify commonly used terms (which today are often used differently) such as manufacturer, distributor and authorised representative so that all stakeholders can be clear on relative responsibilities. Decision No 768/2008/EC also provides the following definitions of terms related to standardisation:

##### a. **Harmonised standard**

Decision No 768/2008/EC introduces a common definition of a harmonised standard in Annex I Chapter R1 in order to clarify this commonly used term.

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<sup>1</sup> 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, OJ L 218/82, 13.08.2008, p. 82

## ANNEX I

### REFERENCE PROVISIONS FOR COMMUNITY HARMONISATION LEGISLATION FOR PRODUCTS

#### Chapter R1

#### Definitions

#### Article R1

#### Definitions

9. *"Harmonised standard" shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive.*

#### **b. Formal objections**

The New Approach directives contain a clause according to which a harmonised standard can be challenged through a formal objection. Decision No 768/2008/EC provides in Article in Annex I, Chapter R3, Article R9 for a “standard” text of such a clause to be applied in all future New Approach Directives:

#### *Formal objection against harmonised standards*

1. *When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in ... [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, hereinafter the "Committee", giving its arguments. The Committee shall deliver its opinion without delay.*
2. *In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.*
3. *The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.*

#### **II. Other legislation**

For information on how to refer to standards in other European legislation, please consult also the document “Methods of referencing standards in legislation with an emphasis on European legislation“ (see Part II, Chapter 2 of the Vademecum).