The Regulatory Approach in the Internal Market

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LEGISLATIVE TOOLS (1)

- REGULATIONS
- DIRECTIVES
- DECISIONS
Technical regulations are normally included in Directives.

Standards are not contained in legislative acts.
A GENERAL OVERVIEW

Non-harmonised → EC Treaty

Harmonised

Old Approach

New Approach
NON-HARMONISED AREAS

The EC treaty:

Article 28
Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Some exceptions:
- protection of health and life of humans, animals or plants;
- protection of industrial and commercial property;
- protection of the environment
HARMONISED AREAS

Old Approach Vs New Approach
THE OLD APPROACH (1)

- Total harmonisation
- One single legislative text
THE OLD APPROACH (2)

- Lengthy approval process
- Very detailed specifications
- Mix of national texts

→ Need for new legislative techniques

- Cassis de Dijon judgement (1979)
SOME STEPS FORWARD

- 1985 Council resolution on **New Approach to technical harmonisation and standards**

- 1986 Single European Act

Internal Market to be completed by end 1992

Free circulation of *(safe)* products
THE NEW APPROACH (1)

- Ease free movement of goods **whilst** ensuring a high level of protection for end users

- Elimination of barriers to trade through harmonised standards
THE NEW APPROACH (2)

Find a balance between

- Free trade
- Trust
- Flexibility
- Controls
- Regulation
- Safety

Consumer protection
**THE NEW APPROACH (3)**

- Essential requirements for products establishing common levels of protection *(compulsory)*
  - Harmonised standards *(voluntary)*
  - Conformity assessment procedures
  - Requirements for Marking
THE NEW APPROACH (4)

Conformity Assessment

(Harmonised) standards

Essential Requirements
THE NEW APPROACH (5)

- Common level of protection for the single market
- Same rules for internal and imported products
- Enhanced safety
- Flexible technology-neutral legal environment
- Alternatives possible
- Reduced burden for enterprises

increased free movement of goods
THE NEW APPROACH (6)

Split responsibilities

Manufacturer’s

PRE-MARKET ASSESSMENT
- Products must fulfil Essential Requirements
- CE marking

Member States

POST-MARKET CONTROL
- Compliance with Essential Requirements
- Market surveillance authorities
THE NEW APPROACH (7)

- Electrical / electronic products
- Pressure equipment / Boilers
- Toys
- Construction products
- Personal protective equipment
- Machinery
- Medical devices
- Radio and telecommunications
- Lifts
- etc ....
CONFORMITY ASSESSMENT PROCEDURES (1)

RELATE TO

- design phase
- production phase
- or both

ARE

- divided into several modules
- a combination of these modules

LEAD TO

- safe marketing of products

(and to CE marking under New Approach Directives)
The relevant procedure is chosen on the basis of the:

- type of product
- nature of the risks involved
- economic infrastructures of the given sector
- types and importance of production
- principle of proportionality

... and it is included in the concerned Directive
Simplified flow chart of conformity assessment procedures under the New Approach
CONFORMITY ASSESSMENT PROCEDURES (4)

Based on the intervention of:

- a first party (manufacturer)
- a third party (notified body)

Supplier Declaration of Conformity
(i.e. toys, electrical equipment)

Certification
(i.e. medical devices, explosives)
THANK YOU

Spanish version available online: