



The Regulatory Approach in the Internal Market

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LEGISLATIVE TOOLS (1)

- **REGULATIONS**
- **DIRECTIVES**
- **DECISIONS**



LEGISLATIVE TOOLS (2)

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

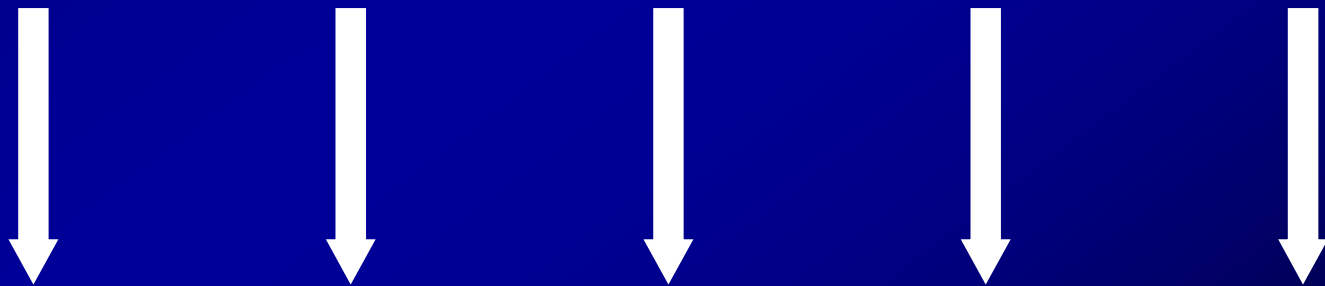
- Cassis de Dijon judgement (1979)



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

controls

flexibility

trust

Consumer
protection

regulation

safety

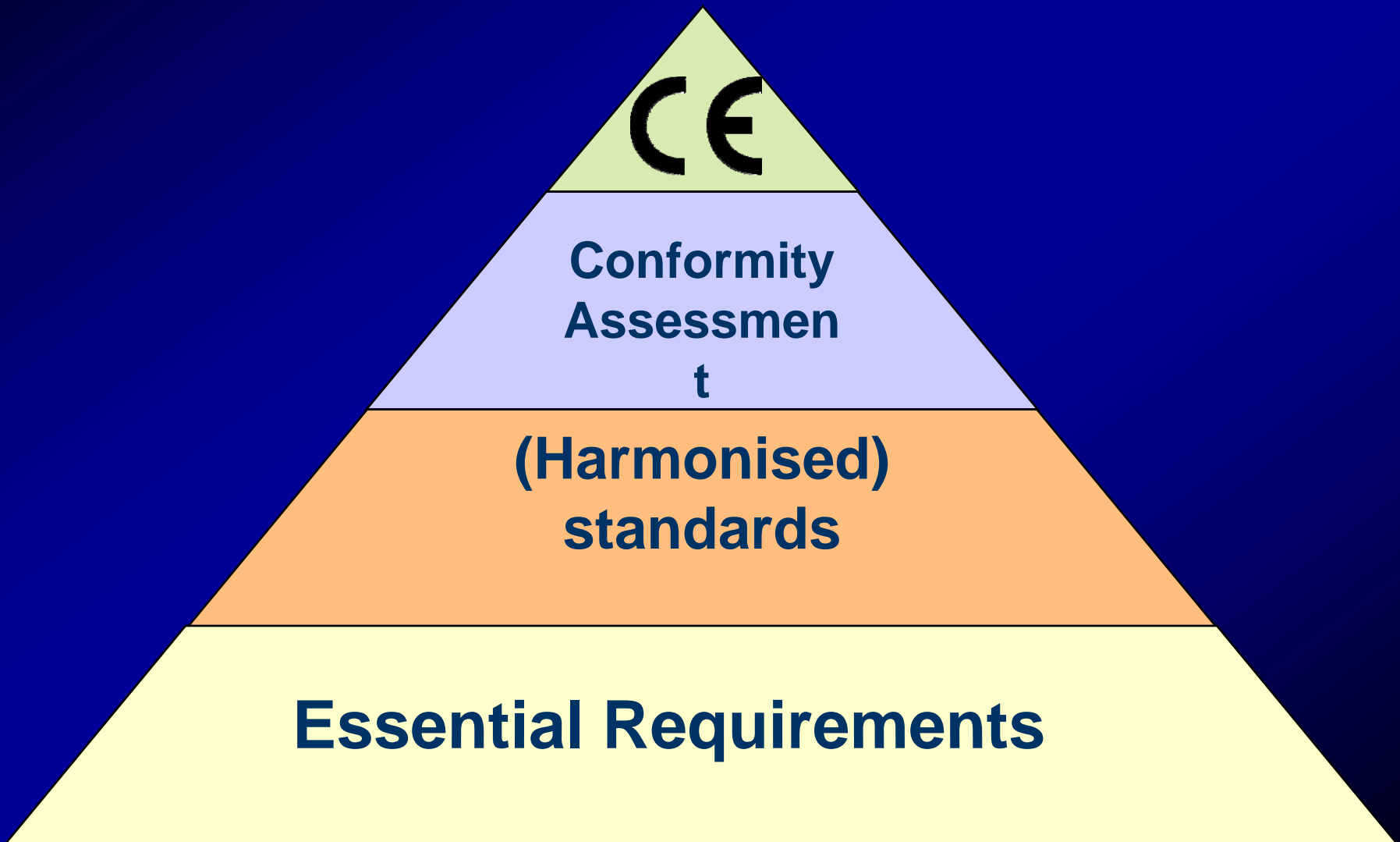


THE NEW APPROACH (3)

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



THE NEW APPROACH (4)





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
-  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  marking under New Approach Directives)



CONFORMITY ASSESSMENT PROCEDURES (2)

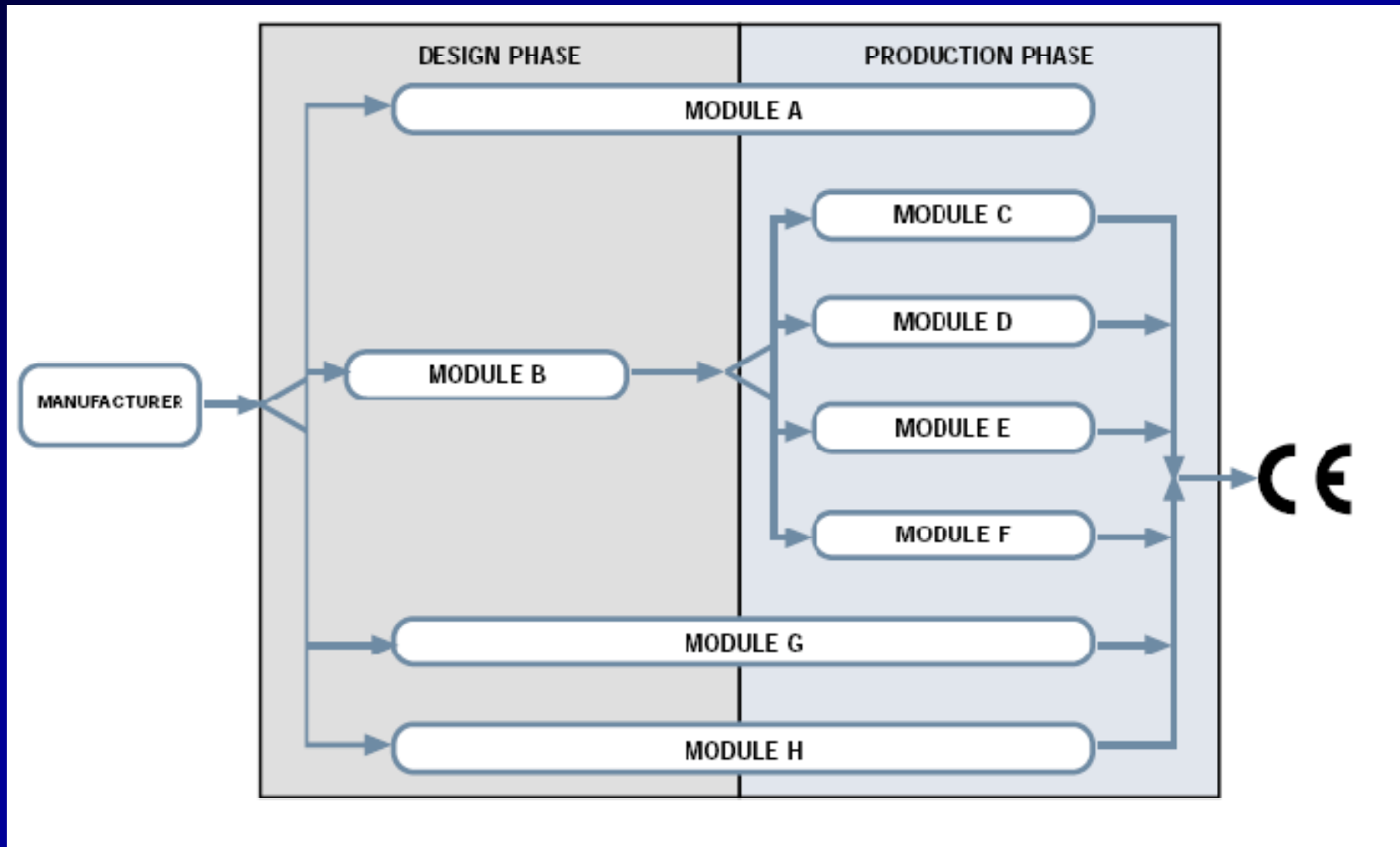
The relevant procedure is chosen on the basis of the:

- **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



CONFORMITY ASSESSMENT PROCEDURES (3)



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)

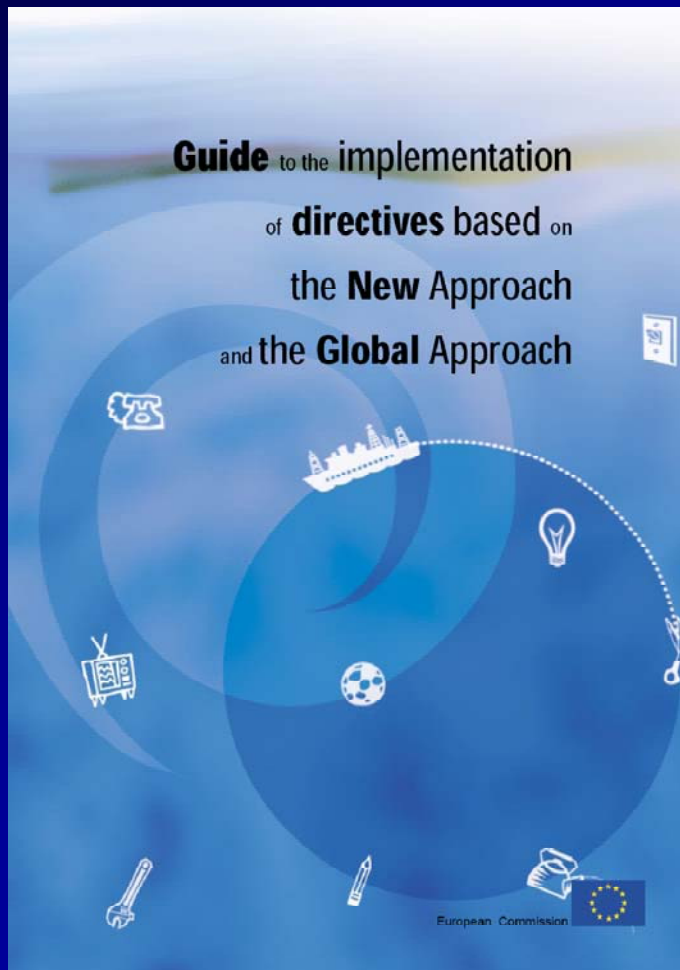


Supplier Declaration of Conformity

Certification

(i.e. toys, electrical equipment)

(i.e. medical devices, explosives)



THANK YOU

Spanish version available online:

http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/allchapters_es.pdf