



THE EUROPEAN LEGISLATIVE FRAMEWORK

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European Commission
Enterprise and Industry

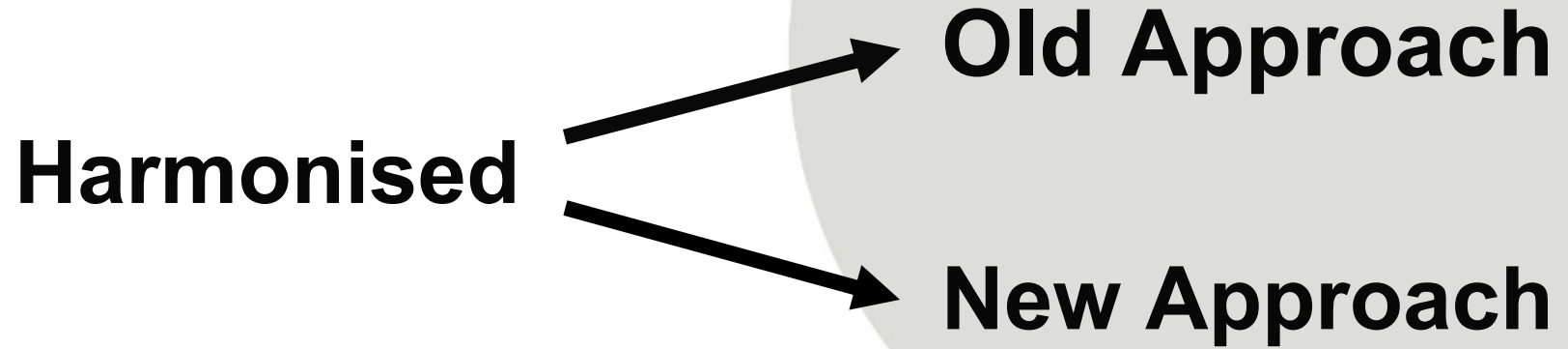


THE SINGLE MARKET

- 27 Member States
- 500 Million Consumers
- Source for growth and jobs
- Wider choice of high quality products
- Competitive environment



A GENERAL OVERVIEW



Non-harmonised → **EC Treaty**

(art. 28 - 30)



HARMONISED AREAS

Old Approach

Vs.

New Approach



LEGISLATIVE TOOLS

Technical Regulations are included in Directives → (compulsory)

Standards are not included in legislative acts → (voluntary)



THE OLD APPROACH (1)

- Detailed harmonisation
- One single legislative text



THE OLD APPROACH (2)

- Very detailed specifications
 - Mix of national texts
 - Lengthy approval process
 - *Cassis de Dijon* judgement (1979)
- Need for new legislative techniques



THE OLD APPROACH (3)

Sensitive sectors

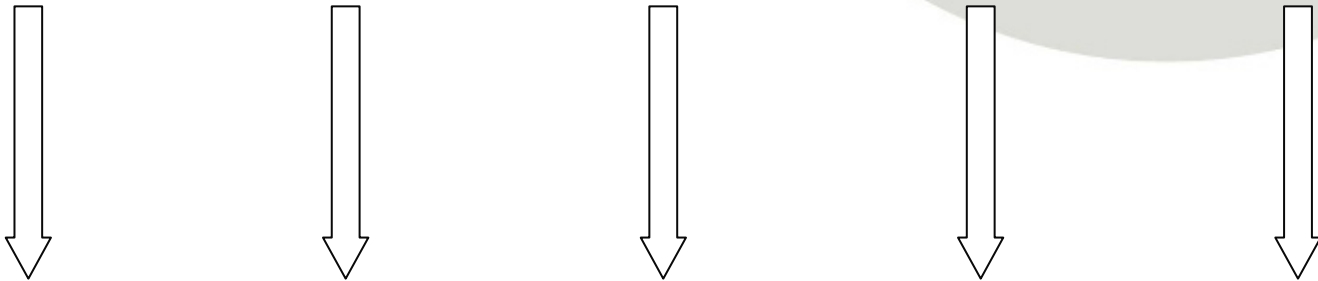
- Automotive
- Chemicals
- Pharmaceuticals



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)

**free
trade**

**affordable
products**

controls

trust

flexibility

**consumer
protection**

regulation

safety



THE NEW APPROACH (3)

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



THE NEW APPROACH (4)

- 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 (5)

Split responsibilities

Manufacturers

PRE-MARKET ASSESSMENT

- Products must fulfil Essential Requirements
-  marking

Member States

POST-MARKET CONTROL

- Compliance with Essential Requirements
- Market surveillance authorities



THE NEW APPROACH (6)

- Electrical / electronic products
- Pressure equipment / Boilers
- Toys
- Construction products
- Personal protective equipment
- Machinery
- Medical devices
- Radio and telecommunications
- Lifts
- etc. ...





STANDARDS

- **Voluntary**
- Developed by **independent** bodies
- Participation open to **all** stakeholders
- In line with **international** standards
- Included in **non-legislative** acts



ACCREDITATION

- Single accreditation bodies
- Non-competition / public authority
- Requirements for accreditation bodies
- Peer evaluation
- Information obligation / transparency
- European Cooperation of Accreditors (EA)



CONFORMITY ASSESSMENT PROCEDURES (1)

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 (2)

Based on the intervention of :

a first party (manufacturer)



Supplier's Declaration of Conformity

(i.e. toys, electrical equipment)

a third party (notified body)



Certification

(i.e. medical devices, explosives)



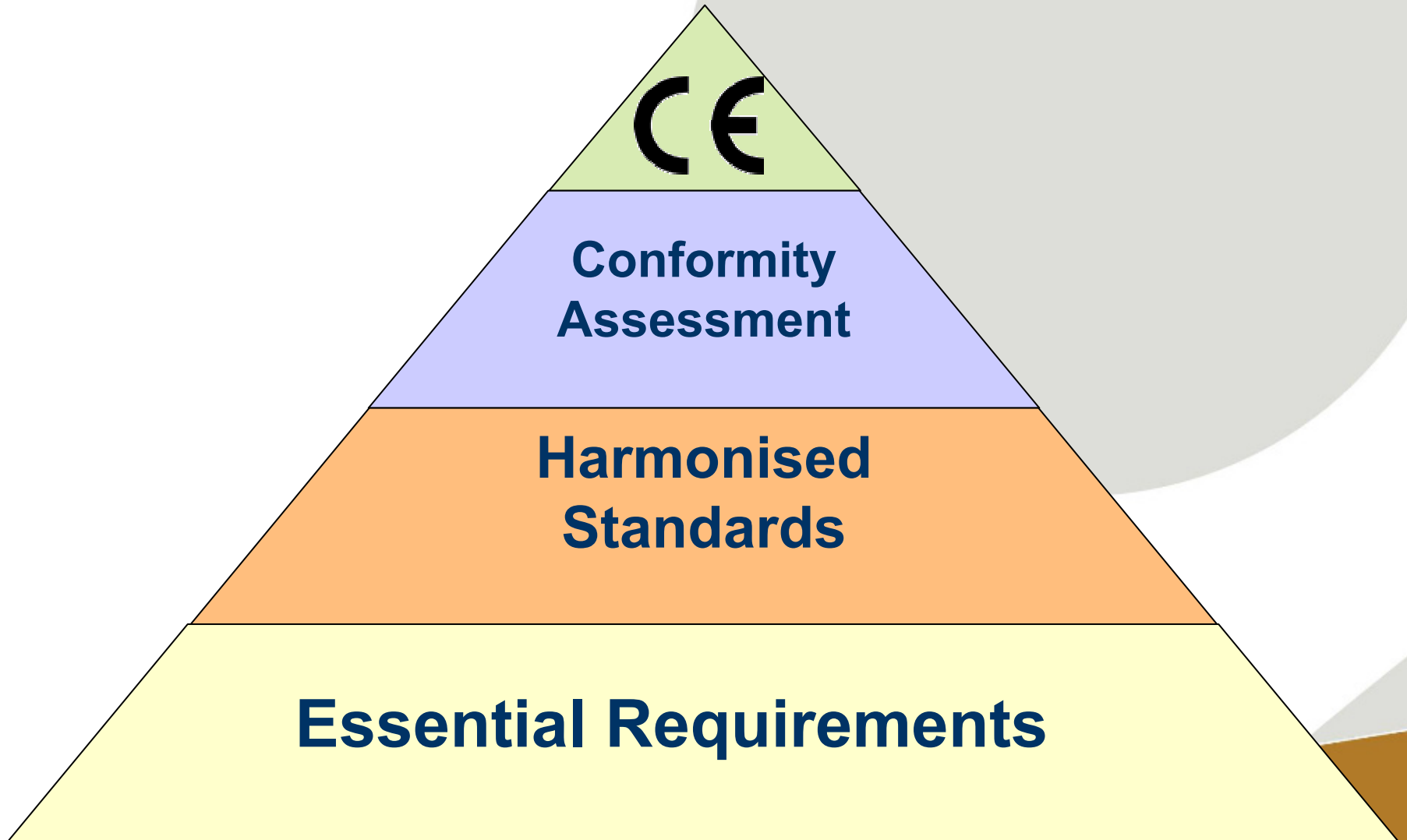
THE OLD APPROACH

**Conformity
Assessment**

**Technical
Requirements**



THE NEW APPROACH



CE

**Conformity
Assessment**

**Harmonised
Standards**

Essential Requirements



MARKET SURVEILLANCE

- Competence of Member States
- Scope
- Organisation / Surveillance measures
- Minimum requirements
- Communication and Co-ordination
- Control of products entering the Community



NON-HARMONISED AREAS (1)

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



NON-HARMONISED AREAS (2)

Directive 98/34/EC

Procedure for the provision of information in the field of technical standards and regulations

A system of notification of technical regulations at a draft stage applying standstill periods during which the European Commission and all Member States can react in a specific form

SCOPE: industrial and agricultural products



DIRECTIVE 98/34/EC

Objectives

- Transparency
- Prevention
- Subsidiarity

Smooth functioning of the Internal Market



DIRECTIVE 98/34/EC

Conditions

- must contain technical regulations
- must be imputable to the state
- must fall outside the “harmonised” area



DIRECTIVE 98/34/EC

Timing for notification

- text must be still at a draft stage
- substantial amendments can still be made
- in any case before its adoption



DIRECTIVE 98/34/EC

Absence of notification

ECJ judgments regarding the procedure

- Inapplicability of non-notified technical regulations
CIA Security (C-194/94)
- Inapplicability of technical regulations adopted during standstill period
Unilever (C-443/98)



DIRECTIVE 98/34/EC

Results

- Transparency
 - TRIS internet site
- Participation
 - stakeholders' comments are welcome
- Efficiency
 - prevention is better than cure



CONCLUSIONS

THE SINGLE MARKET

- Free circulation both in harmonised and non-harmonised areas
- Balance between ex-ante and ex-post controls
- Market operators and regulators are equally involved
- Fair balance between regulation, control and freedom
- Among the best in terms of safety, choice and price of products



LINKS

New Approach

http://ec.europa.eu/enterprise/newapproach/index_en.htm

New Internal Market Package for Goods

http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm

Directive 98/34/EC

<http://ec.europa.eu/enterprise/tris>

Questions

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THANK YOU



European Commission
Enterprise and Industry