

# **CONFORMITY ASSESSMENT IN EU TECHNICAL HARMONISATION LEGISLATION**

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**Fabrizio SACCHETTI**



**European Commission**  
Enterprise and Industry



# OUTLINE

- I. Overview of the EU legal framework for technical harmonisation
- II. The EU conformity assessment system
- III. SDoC – Let's take a closer look
- IV. Case study 1 – Electrical equipment
- V. Case study 2 – Toys
- VI. Conclusions



**I.**

# **Overview of the EU legal framework for technical harmonisation**



# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

## HARMONISED vs NON-HARMONISED

**Harmonised**



**Old Approach**



**New Approach**

**Non-harmonised**

**EC Treaty**

(articles 28 and 30 – Mutual recognition of national regulations ensures free movement within the EU internal market)

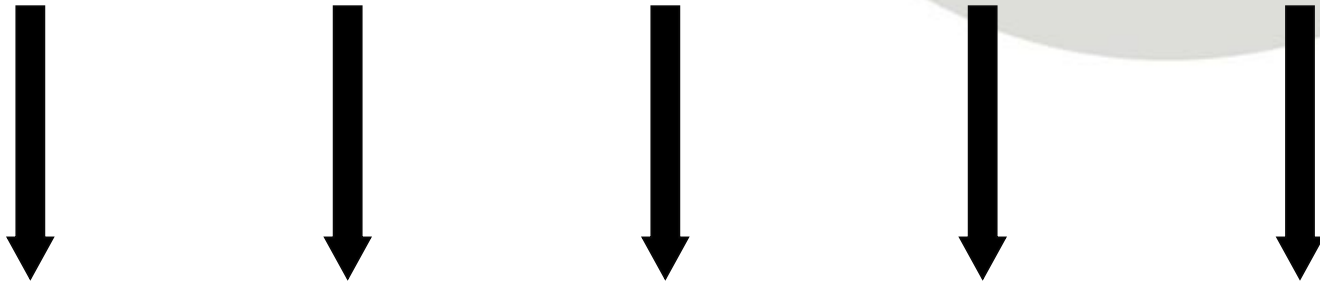


## OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

### 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

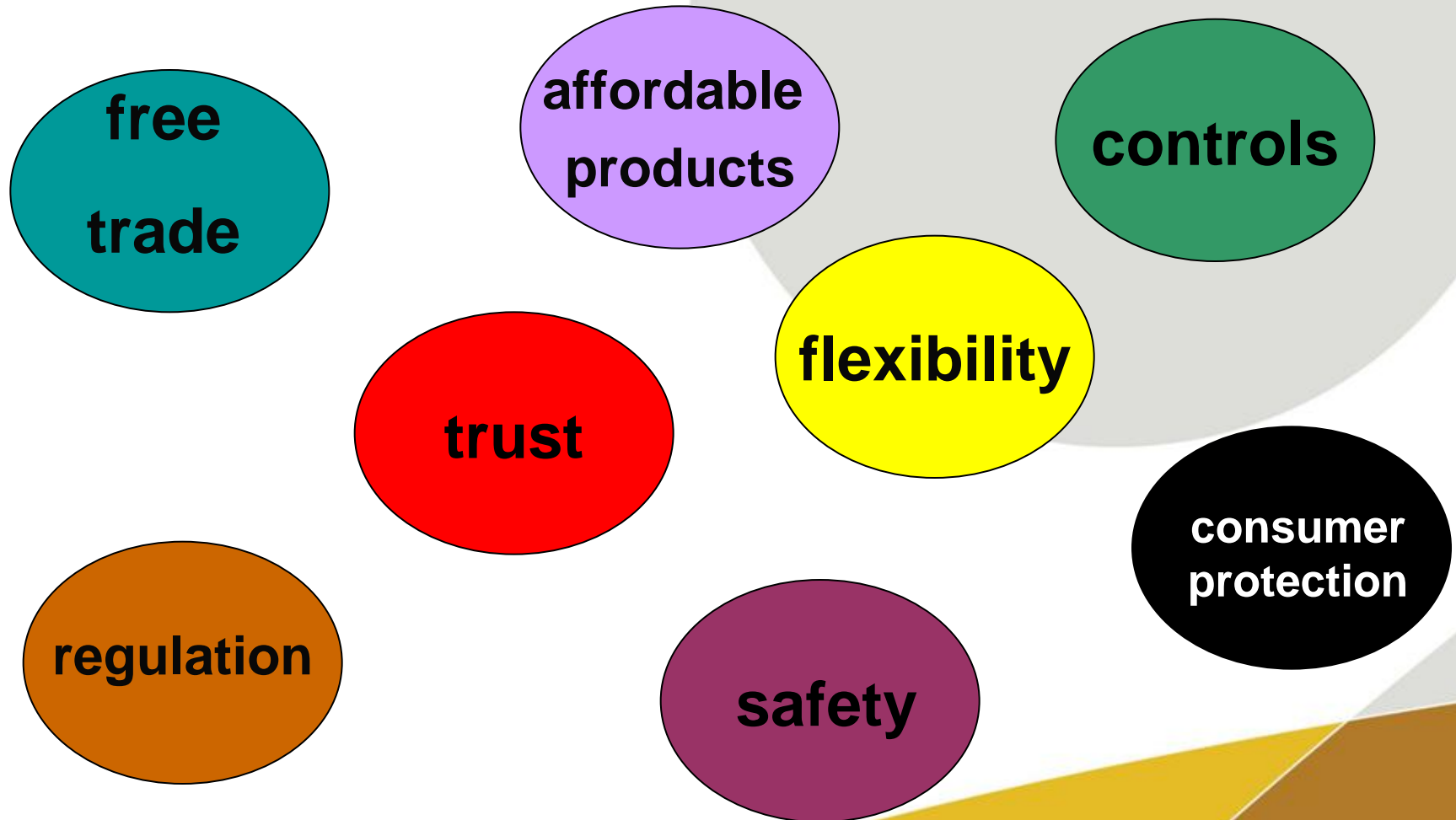


Free circulation of (safe) products



# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

## THE NEW APPROACH (1)





# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION


## THE NEW APPROACH (2)

- **Ease free movement of goods** **whilst** ensuring a **high level of protection** (health & safety, environment, etc.)
- **Essential requirements** expressed in terms of performance indicators or objectives for products establishing common levels of protection (**compulsory**)
  - Manufacturers shall ensure, when placing their products on the market, that they have been designed and manufactured in accordance with the **requirements** set out in the legislation
  - **Essential requirements** should be worded precisely enough in order to create legally binding obligations. They should be formulated so as to enable the assessment of conformity with those requirements even in the absence of harmonised standards or in case in which the manufacturer chooses not to apply the latter. The degree of detail of the wording will depend on the characteristics of each sector.



# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

## THE NEW APPROACH (3)

- **Harmonised standards** detailing technical solutions to meet the essential requirements (**voluntary**, manufacturers can use other methods)
  - Task sharing
  - Legislation : safeguard public interest
  - Standards : harmonise technical specifications
- **Common set of conformity assessment procedures** (the so-called "**Modules**")
- **Uniform rules for the designation and supervision of Notified Bodies**
- **Requirements for**  **Marking**
- **Market surveillance**



# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

## THE NEW APPROACH (4)

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



## OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

### THE NEW APPROACH (5)

- Electrical / electronic products
- Pressure equipment / Gas appliances
- Toys
- Personal protective equipment
- Machinery
- Medical devices
- Radio and telecom equipment
- Lifts
- ATEX equipment
- Recreational craft
- etc. ...





# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

## EUROPEAN HARMONISED STANDARDS

- **Voluntary**
- Developed by **independent** bodies (CEN, CENELEC, ETSI)
- Participation open to **all** stakeholders, consensus-based process
- Based on relevant **international** standards
- Confer **presumption of conformity** with:
  - the essential requirements for products (health & safety, environment, etc.) covered by the harmonised standards - References of relevant harmonised standards are published in OJEU
  - Requirements for accreditation bodies and notification bodies (see list of relevant harmonised standards published in OJEU C 136, 16.6.2009, p. 29)



## OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

### THE NEW LEGISLATIVE FRAMEWORK

- [Regulation 765/2008/EC](#) - requirements for **accreditation** and **market surveillance** relating to the marketing of products
- [Decision 768/2008/EC](#) - a **common framework** for the **marketing of products**

[Official Journal of the EU, L218, 13.08.08](#)



# OVERVIEW OF EU LEGAL FRAMEWORK FOR TECHNICAL HARMONISATION

## THE NEW LEGISLATIVE FRAMEWORK (2)

### REGULATION

- Accreditation
- Market Surveillance
  - Internal
  - Imported products
- **CE** General principles
- Financing elements

**Applicable 1 Jan 2010**

### DECISION

- Definitions
- Obligations for economic operators
- Conformity Assessment Procedures
- **CE** marking
- Notified bodies
- Safeguard mechanisms

**Basis for future legislation**



**II.**

**The EU conformity assessment system**  
(the need to strike a fair balance between  
pre-market and post-market control)



# THE EU CONFORMITY ASSESSEMENT SYSTEM

## THE NEED FOR A SAFE ENVIRONMENT

- Ensure safety
- Protect consumers
- Enhance trust
- Avoid distortion of competition
- Guarantee equal treatment

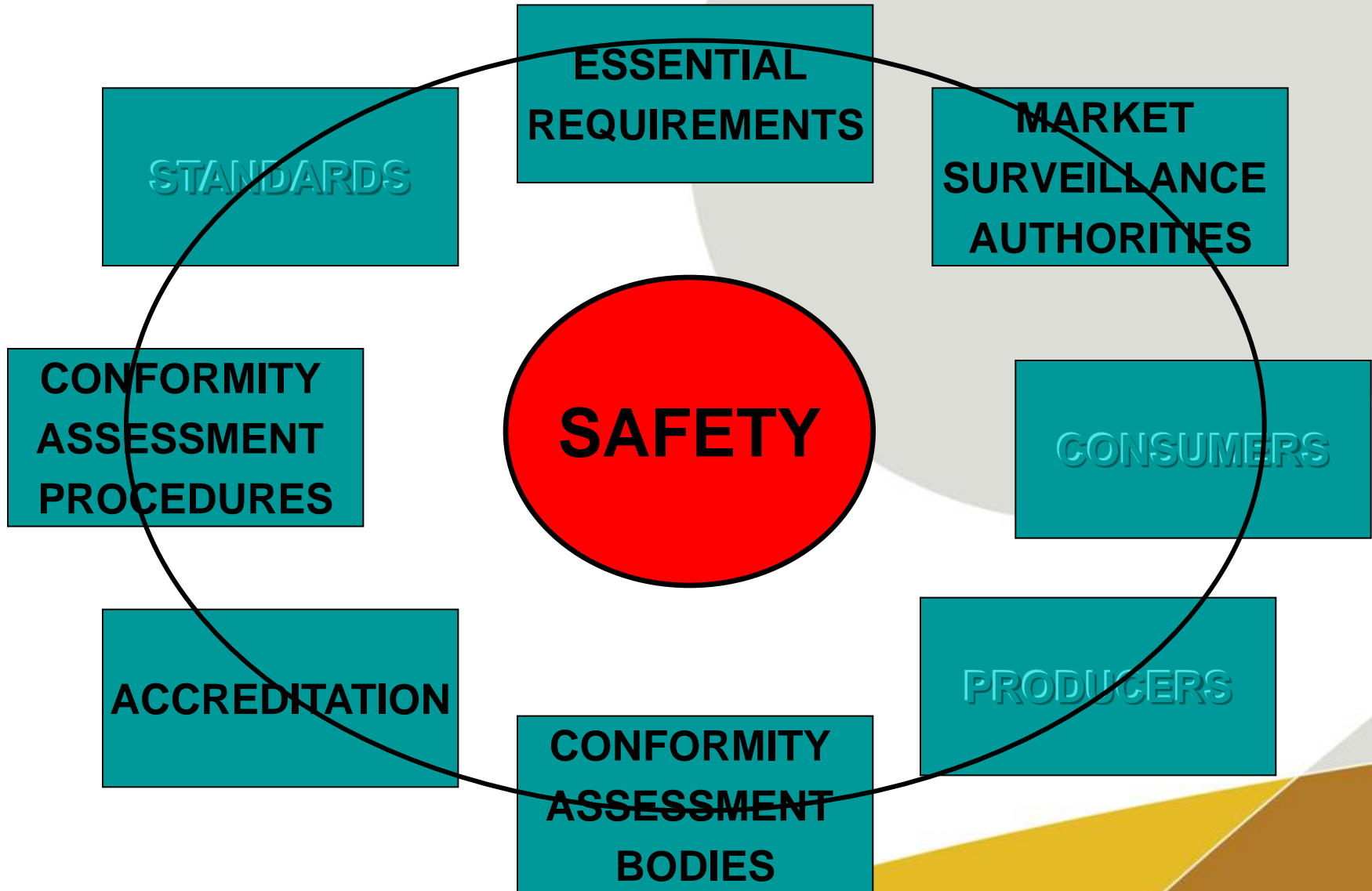
...but:

- No single solution
- Combination of several tools



# THE EU CONFORMITY ASSESSMENT SYSTEM

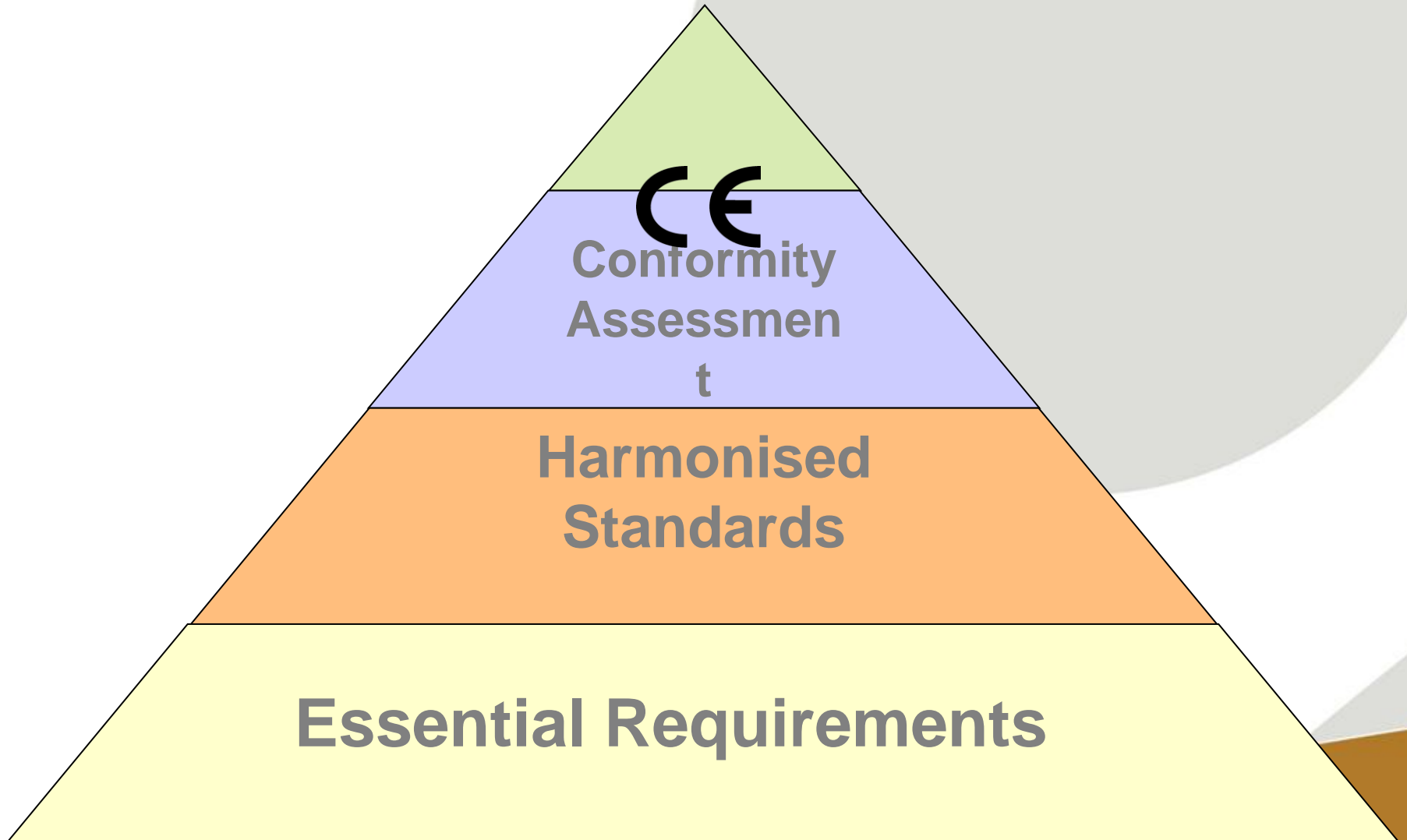
## AN INTERCONNECTED SYSTEM





# THE EU CONFORMITY ASSESSMENT SYSTEM

## THE NEW APPROACH





# THE EU CONFORMITY ASSESSMENT SYSTEM

## THE NEW LEGISLATIVE FRAMEWORK (1)

### Regulation 765/2008

- **Common framework for accreditation**
- **Common framework for market surveillance**



## THE EU CONFORMITY ASSESSMENT SYSTEM

### THE NEW LEGISLATIVE FRAMEWORK (2)

## Decision 768/2008

- **Modernise conformity assessment modules** initially set out in Council Decision 93/465/EEC, also in light of relevant ISO/IEC standards (17000 series) and guides
- **Choice of clear, transparent and coherent conformity assessment procedures, restricting the possible variants**
- **Menu of modules**, enabling the legislator to choose a procedure from the least to the most stringent, in **proportion to the level of risk involved and the level of safety required**

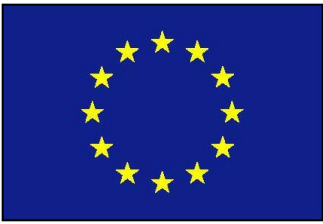


# THE EU CONFORMITY ASSESSMENT SYSTEM

## THE NEW LEGISLATIVE FRAMEWORK (3)

### Decision 768/2008

- **Avoid creating unnecessary burdens for economic operators**
  - ⇒ choice of appropriate conformity assessment procedure based on a regulatory impact assessment (=> more detailed and coherent selection criteria)
  - ⇒ special attention to SMEs' situation
- **Ensure uniformity in the assessment of conformity assessment bodies** (=> accreditation)
- **Ensure a uniform high level of performance of notified bodies** throughout the EU (=> strengthened supervision by Member States) and **consistency in the application of the modules** (=> coordination and cooperation mechanisms between notified bodies)



# THE EU CONFORMITY ASSESSMENT SYSTEM

## PRE-MARKET CONTROLS (1)

### CONFORMITY ASSESSMENT PROCEDURES

- **Criteria for the choice of the relevant procedure:**
  - **Appropriate to the type of product**
  - **nature and level of risk involved**
  - **when 3rd party involvement is mandatory**
    - ⇒ **Manufacturer must be given the choice between quality assurance and product certification modules**
  - **proportionate and effective**
    - ⇒ **economic infrastructure of the given sector (e.g. type and size of companies, complexity of product technology)**
    - ⇒ **type and importance of production**



# THE EU CONFORMITY ASSESSMENT SYSTEM

## PRE-MARKET CONTROLS (2)

### CONFORMITY ASSESSMENT PROCEDURES

- **Procedures divided into 8 different modules**
- **Modules range from manufacturer's declaration to full quality assurance certification**
- **Range of options set in Directives**
- **All procedures give equivalent results: presumption of conformity**

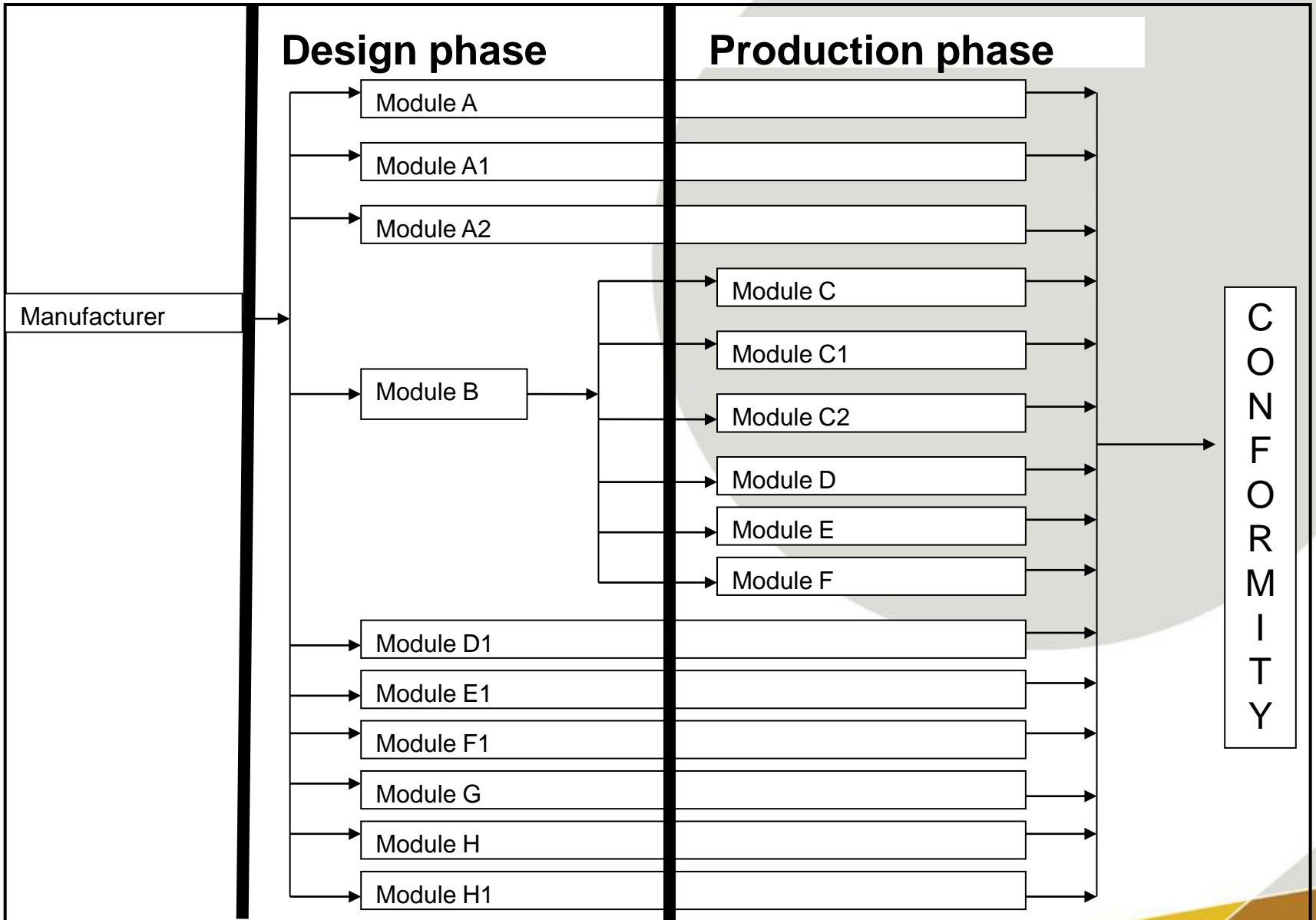


# THE EU CONFORMITY ASSESSMENT SYSTEM

## PRE-MARKET CONTROLS (3)

### CONFORMITY ASSESSMENT MODULES

- **A Internal production control**
- **B EC type examination**
- **C Conformity to type**
- **D Production quality assurance**
- **E Product quality assurance**
- **F Product verification**
- **G Unit verification**
- **H Full quality assurance**



# CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

<p>A. Internal production control)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Keeps technical documentation at the disposal of national authorities</li> </ul>	<p style="text-align: center;">B. (type examination)</p> <hr/> <p>Manufacturer submits to notified body</p> <ul style="list-style-type: none"> <li>&gt; Technical documentation</li> <li>&gt; Supporting evidence for the adequacy of the technical design solution</li> <li>&gt; Specimen(s), representative of the production envisaged, as required</li> </ul> <p>Notified body</p> <ul style="list-style-type: none"> <li>&gt; Ascertains conformity with essential requirements</li> <li>&gt; Examines technical documentation and supporting evidence to assess adequacy of the technical design</li> <li>&gt; For specimen(s): carries out tests, if necessary</li> <li>&gt; Issues EC type-examination certificate</li> </ul>				<p>G. Unit verification</p> <p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Submits technical documentation</li> </ul>		<p>H. (full quality assurance)</p> <p>EN ISO 9001:2000</p> <p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Operates an approved quality system (QS) for design</li> <li>&gt; submits technical documentation</li> </ul> <p>Notified Body</p> <ul style="list-style-type: none"> <li>&gt; Carries out surveillance of the QS</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>H1</p> <p>Notified body</p> <ul style="list-style-type: none"> <li>&gt; Verifies conformity of design(1)</li> <li>&gt; Issues EC-design examination certificate (1)</li> </ul> </div>
<p>A. Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Declares conformity with essential requirements</li> <li>&gt; Affixes the required marking</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>A1:</p> <p>Accredited in-house body</p> </div> <p>or notified body</p> <ul style="list-style-type: none"> <li>&gt; Tests on specific aspects of the product (1)</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>A2:</p> <ul style="list-style-type: none"> <li>&gt; Product checks at random intervals (1)</li> </ul> </div>	<p>C. (conformity to type)</p> <p>C. Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Declares conformity with approved type</li> <li>-&gt; Affixes required marking</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>C1:</p> <p>Accredited in-house body</p> </div> <p>or notified body</p> <ul style="list-style-type: none"> <li>&gt; Tests on specific aspects of the product (1)</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>C2:</p> <ul style="list-style-type: none"> <li>&gt; Product checks at random intervals (1)</li> </ul> </div>	<p>D. Production quality assurance</p> <p>EN ISO 9001:2000</p> <p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Operates an approved quality system (QS) for production and testing</li> <li>&gt; Declares conformity with approved type</li> <li>&gt; Affixes the required marking</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>D1:</p> <p>Declares conformity to essential requirements</p> <ul style="list-style-type: none"> <li>&gt; Affixes required marking</li> </ul> </div> <p>Notified Body</p> <ul style="list-style-type: none"> <li>&gt; Approves the QS</li> <li>&gt; Carries out surveillance of the QS</li> </ul>	<p>E. Product quality assurance</p> <p>EN ISO 9001:2000</p> <p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Operates an approved quality system for inspection and testing</li> <li>&gt; Declares conformity with approved type,</li> <li>&gt; Affixes the required marking</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>E1:</p> <p>Declares conformity to essential requirements</p> <ul style="list-style-type: none"> <li>&gt; Affixes required marking</li> </ul> </div> <p>Notified Body</p> <ul style="list-style-type: none"> <li>&gt; Approves the QS</li> <li>&gt; Carries out surveillance of the QS</li> </ul>	<p>F. (product verification)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Declares conformity with approved type</li> <li>&gt; Affixes the required marking</li> </ul> <div style="background-color: orange; padding: 5px;"> <p>F1:</p> <p>Declares conformity to essential requirements</p> <ul style="list-style-type: none"> <li>&gt; Affixes required marking</li> </ul> </div> <p>Notified Body</p> <ul style="list-style-type: none"> <li>&gt; Verifies conformity with essential requirements</li> <li>&gt; Issues certificate of conformity</li> </ul>	<p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Submits product</li> <li>&gt; Declares conformity</li> <li>&gt; Affixes the required marking</li> </ul> <p>Notified body</p> <ul style="list-style-type: none"> <li>&gt; Verifies conformity with essential requirements</li> <li>&gt; Issues certificate of conformity</li> </ul>	<p>Manufacturer</p> <ul style="list-style-type: none"> <li>&gt; Operates an approved QS for production and testing</li> <li>&gt; Declares conformity</li> <li>&gt; Affixes the required marking</li> </ul> <p>Notified body</p> <ul style="list-style-type: none"> <li>&gt; Carries out surveillance of the QS</li> </ul>	



## THE EU CONFORMITY ASSESSMENT SYSTEM PRE-MARKET CONTROLS (4)

### ACCREDITATION

**Preferred tool for the assessment of the technical competence of conformity assessment bodies in regulated areas**

**=> last level of control providing confidence in the conformity assessment system**

**=> tool to create confidence in conformity certificates and thus establish trust in the marketplace**



## THE EU CONFORMITY ASSESSMENT SYSTEM PRE-MARKET CONTROLS (5)

### CONFORMITY ASSESSMENT BODIES

- **Issue certification**
  - ⇒ possibility of sub-contracting specific tasks but notified bodies retain ultimate responsibility
- **Independent / no conflict of interests**
- **Accredited in their EU Member State**
- **Designated and notified by a public authority in an EU Member State**
- **Competition in the Single Market**
- **Free prices policy**



# THE EU CONFORMITY ASSESSMENT SYSTEM

## POST-MARKET CONTROLS

### MARKET SURVEILLANCE

- **Responsibility of Members States**
- **Public authority**
- **Organisation / Surveillance measures**
- **Minimum requirements**
- **Communication and Co-ordination**



# THE EU CONFORMITY ASSESSMENT SYSTEM

## SHARED RESPONSIBILITIES

### **Manufacturers**

#### **PRE-MARKET ASSESSMENT**

- **Products must fulfil Essential Requirements**
- **Products need to be tested**

### **Member States**

#### **POST-MARKET CONTROL**

- **Compliance with Essential Requirements**
- **Market surveillance authorities**



**III.**  
**SDoC – Let's take a  
closer look**



# SDoC (1) - What it is

- **Defined under Decision 768/2008** “on a common framework for the marketing of products”
  - ⇒ Module A - Internal production control
  - ⇒ Module A1 - Internal production control plus supervised product testing
  - ⇒ Module A2 - Internal production control plus supervised product checks at random intervals
  - ⇒ and Module C - Conformity to type based on internal production control
- The manufacturer fulfils the legislative requirements applying to a product and declared on his sole responsibility that the product concerned satisfies the requirements of the legislative instrument that apply to it
- No Conformity Assessment Bodies involved for Modules A, C
- **Important: manufacturers must perform a safety assessment + establish a technical file demonstrating all measures taken to ensure compliance**



## SDoC (2) – Selection Criteria

### **Basic criteria:**

- Level of risk + level of protection
- Known / unknown technology - Availability of standards
- Industrial infrastructure (coherence + SME friendly)
- Availability of independent testing laboratories

### **Accompanying measures:**

- Effective enforcement by public authorities (=> post-market surveillance), including on products from 3rd countries
- Adequate product liability regime



# SDoC (3) - Manufacturer's Liability

**Product Liability**  
(EU Directives 85/374/EEC,  
1999/34/EC)

**Enforced  
by the Member States**

**Certification bodies  
do not carry any  
liability**

**Manufacturers  
a l w a y s  
l i a b l e !**

**Additional  
national regulations  
as may apply**

**Regulations and  
jurisdiction in  
all other countries**



## SDoC (4) – Benefits

- Faster time to market
- Cheaper procedure
- Avoidance of unnecessary duplication of mandatory Third Party assessment
- Incentive to build know-how management
- Possibility of in-house testing



## SDoC (5) – Technical documentation

- The manufacturer draws up the technical documentation of the product
- Technical documentation is the technical file that provides information on the design, manufacture and operation of the product
  - A main purpose of drafting the technical documentation is to provide supporting evidence of the conformity of the product in question
  - Technical documentation accompanies the SDoC
  - The content of the technical documentation as set out in the text of the Decision 768/2008 is based on EN ISO 17050-2:2004 ( § 5.1) that specifies requirements for documentation in support of the declaration of conformity



## SDoC (6) – Technical documentation

The technical documentation shall contain, wherever applicable, at least the following elements :

- a general description of the product
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- **descriptions and explanations** necessary for the understanding of those drawings and schemes and the operation of the product
- **a list of the harmonised standards and/or other relevant technical specifications** the references of which have been published in the Official Journal of the European Union and **descriptions of the solutions adopted to meet the essential requirements** of the legislative instrument where those harmonised standards have not been applied
  - In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied
- results of design calculations made, examinations carried out, etc.
- test reports



## SDoC (7) - Examples of sectors

- Electrical / electronic products / machinery
- Radio and telecommunications
- Low voltage
- Electromagnetic compatibility
- Medical devices (some categories)
- Refrigeration appliances
- Pressure equipment (some categories)



*More under*

[http://ec.europa.eu/enterprise/newapproach/index\\_en.htm](http://ec.europa.eu/enterprise/newapproach/index_en.htm)



# IV.

## Case study 1

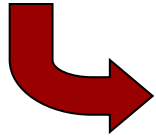
### Electrical equipment



# Safety of electrical products

1

**The Low Voltage Directive (LVD) 2006/95/EC**  
(adopted on 19th February 1973 as 73/23/EEC,  
recast in 2006)



Based on article 95 of the EC treaty; purpose is to permit *free movement* of electrical equipment in Europe



“**Total harmonisation**” and “**Total Safety**” Directive



Applies to **electrical equipment** designed for use with a voltage rating of **[50, 1000] V (AC)** **[75, 1500] V (DC)**



# Safety of electrical products

## The Low Voltage Directive (LVD) 2006/95/EC

2



Guidelines on the application of the Low Voltage Directive  
- LVD



Large system of European electro technical standards  
based on international standards (~700);



Decreasing number of fatal accidents in the last 25 years  
by electrocution;



# Conformity assessment

## Internal production control

- **Technical documentation**
  - to be kept for 10 years
  - to enable the assessment of the conformity of the electrical equipment to the requirements to the Directive
- **Manufacturing process shall ensure compliance of the manufactured products with the technical documentation**



# Conformity assessment

## Internal production control (Module A)

Procedure whereby the manufacturer ensures and declares that the electrical equipment satisfies the requirements of the Directive

=> EC declaration of conformity + CE marking



# Overall assessment

- All available indicators (safeguard actions, RAPEX notifications, accident data) show a **very satisfactory level of compliance**
- **Some critical product families:** low priced and low tech consumer products, mostly imported (e.g. cord extension sets and multiple socket cord outlets)
- Another critical issue: **unsafe counterfeited products**
- **Intensified market surveillance efforts in product areas of concern, including reinforced controls at the EU external border**



# V.

## Case study 2

### Toys



## **CONFORMITY ASSESSMENT FOR TOYS**

### **Current Toy Safety Directive 88/378/EEC**

**Choice of the conformity assessment  
procedure**

- 1) Self verification (Module A) if**
  - harmonised standard covering all safety aspects are complied with**
  
- 2) Third party verification (EC type examination) if**
  - harmonised standards do not exist**
  - harmonised standards are not applied or only in part**
  - harmonised standards are published with a restriction**
  - manufacturers considers that toy necessitates 3rd party verification**

### **New Toy Safety Directive 2009/48/EC extends with**

**Explicit obligation to carry out  
an analysis of hazards  
and detail it in a  
comprehensive safety  
assessment to be part of the  
product technical file**



## **CONFORMITY ASSESSMENT FOR TOYS**

- **No complex technology**
- **Compromise: SDoC only where harmonised standards exist that cover all relevant essential health and safety requirements**
- **Where harmonised standards exist, risks are manageable by manufacturers**
- **Strong and well-developed market surveillance**
- **No evidence that more stringent conformity assessment would yield higher levels of compliance**



# VI. Conclusions



## CONCLUSIONS

- EU experience shows that it is possible to **attain a very high level of protection whilst ensuring a fair balance between pre-market and post-market controls**
- **Use Good Regulatory Practice principles and tools** (=> regulatory impact assessments) in the choice of conformity assessment procedures
- Any type of conformity assessment procedure requires an **adequate level of post-market surveillance**
- **Reputation is a value**: serious manufacturers will always strive for compliance!
- **Fair balance between regulation, control and freedom**



# LINKS

New Approach:

[http://ec.europa.eu/enterprise/newapproach/index\\_en.htm](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](http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm)

Market Surveillance:

[http://ec.europa.eu/enterprise/newapproach/market\\_surveillance.htm](http://ec.europa.eu/enterprise/newapproach/market_surveillance.htm)

Questions

[fabrizio.sacchetti@ec.europa.eu](mailto:fabrizio.sacchetti@ec.europa.eu)

# **CONFORMITY ASSESSMENT IN EU TECHNICAL HARMONISATION LEGISLATION**

## **THANK YOU**