



## **History New and Global approach**

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## Before 1985

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Product directives contained:

- ▶ detailed technical specifications
- ▶ third party examination of final product
- ▶ no modern manufacturing processes taken into account

### Consequences

- ▶ legislation outdated
- ▶ a hinder for innovation
- ▶ no modern conformity assessment procedures
- ▶ launching on the market of (new) products delayed



# 1985: New and Global Approach

**Global approach:** conformity assessment procedures

- ▶ reinforce role and responsibility of manufacturer
- ▶ takes into account quality assurance principles.
- ▶ as little intervention of notified body as possible
- ▶ intervention at the level of production or final product control.

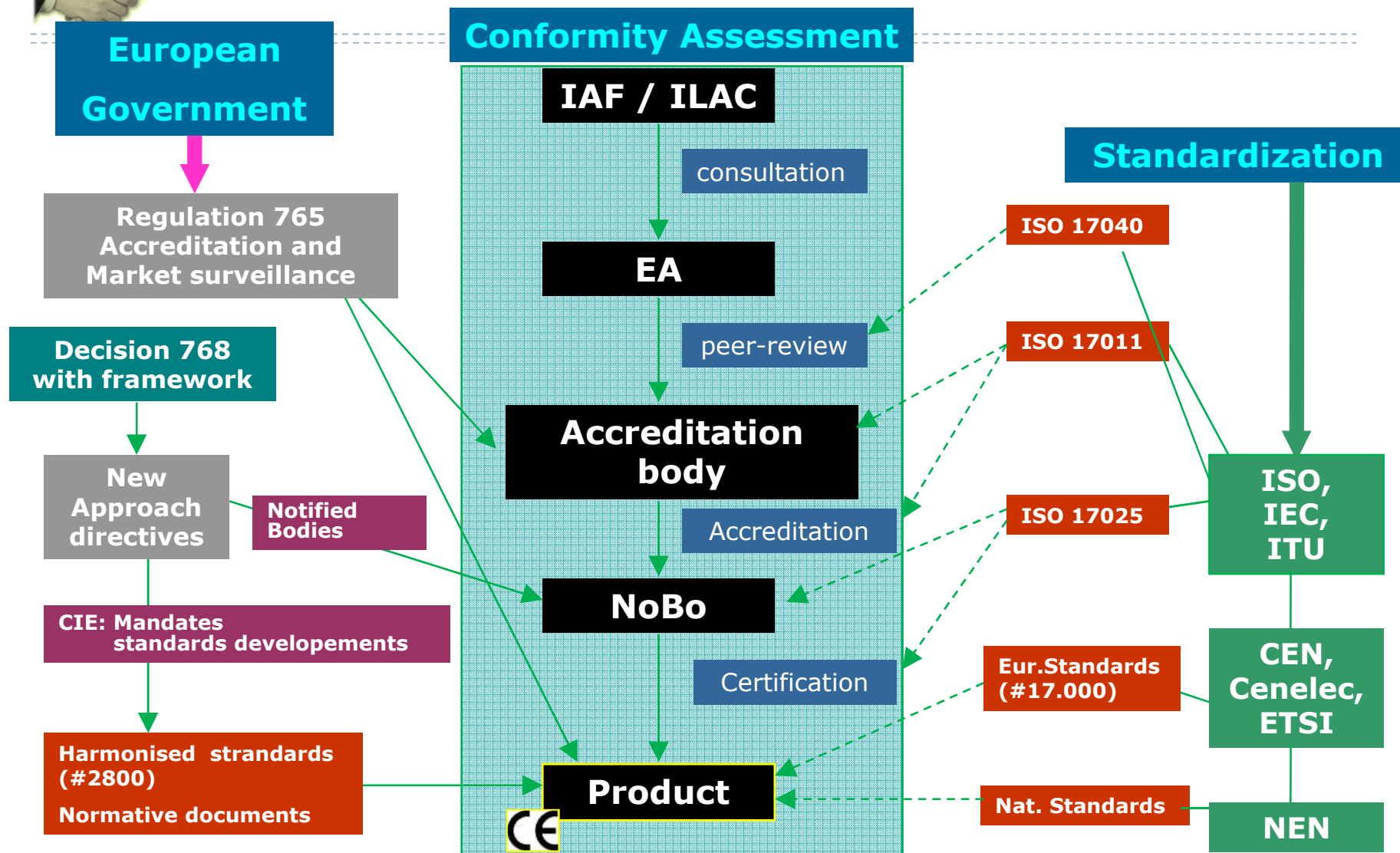
**New approach :** legal requirements for products

- ▶ restricted to essential requirements
- ▶ no technical solutions in legislation
- ▶ not too specific to avoid interference with technical process.
- ▶ expressed in the form of performances requirements.
- ▶ Detailed technical issues in harmonised European standards

“Global and New Approach” nowadays often referred to as “New Approach”.



# Structure New Approach





## 2003/2004

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### **May 2003:**

Communication from Commission to Counsel and European Parliament:  
“Enhancing the implementation of the new approach Directives”

### **November 2003:**

The Counsel acknowledge the importance of the New Approach but also recognized the need for a clearer framework for conformity assessment, accreditation and market surveillance.

### **2004:**

Stocktaking exercise on experience with the new approach.



# Conclusions inventory

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New Approach legislation is at large successful:

- ▶ internal market for goods is a reality.
- ▶ protection of public interests at a high level (health safety, consumer protection, etc)
- ▶ free movement of goods due to harmonised conditions.

Shortcomings:

- ▶ Significant number of non-compliant products
- ▶ Unsatisfactory performance of certain notified bodies
- ▶ Application unnecessarily complicated by inconsistency in the legislation.



# Shortcomings

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## Risks by non-compliance

- ▶ Harmful for product users (electric shock or burns, incorrect measurement result, explosion of boiler)
- ▶ Unfair competition (avoid cost conformity assessment procedures, direct access to market)

## Major reasons for non-compliance:

- ▶ failing market surveillance.
- ▶ legislation focus on manufacturer and not on the rest of the supply chain.



# Shortcomings

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## Performance of (certain) Notified bodies

- ▶ lack of necessary competence
- ▶ insufficient effort into assessment or application of procedures

## Inconsistency between directives

- ▶ different terminology
- ▶ (slight) variation in procedures
- ▶ room for interpretation in definition/legal provisions

As more than one directive applies to a product

inconsistency leads to confusion and legal uncertainty





## 2010: New Legal Framework

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New instruments to strengthen and complete existing rules:

Regulation 756/2008 setting out requirements for accreditation and market surveillance relating to the marketing of products

- ▶ applicable since 1 January 2010

Decision 768/2008 on a common framework for the marketing of products.

- ▶ Toolbox for existing and future legislation



## 2014: State of play

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- ▶ Several directives under discussion to align with NLF (recreational crafts, radio equipment, pressure equipment, marine equipment, etc)
- ▶ Omnibus: alignment 9 directives with Decision 768/2009 almost finished, just waiting for formal approval and publication.
- ▶ Member States should start implementing 9 directives of Omnibus.
- ▶ Implementation should be finished 2 years after entry into force of directive (probably early 2016).

Are there any questions?